Iowa Medicaid Drug Prior Authorization Criteria

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

ADD/ADHD/ NARCOLEPSY AGENTS *Use CNS Stimulants and Atomoxetine PA form*	*See CNS Stimulants and Atomoxetine Prior Authorization Criteria.*
Age Edit Override – Codeine or Tramadol *Use Age Edit Override-Codeine or Tramadol PA form*	An age edit override for codeine or tramadol is required for patients under 18 years of age. Payment will be considered under the following conditions: 1. Member is 12 years of age or older; and 2. Medication is not being prescribed to treat pain after surgery following tonsil and/or adenoid procedure for members 12 to 18 years of age; and 3. If member is between 12 and 18 years of age, member is not obese (BMI greater than 30kg/m^2), does not have obstructive sleep apnea, or severe lung disease.
Alpha$_2$ Agonists, Extended-Release ***Intuniv™*** ***Kapvay™*** *Use Alpha$_2$ Agonists, Extended-Release PA form*	Prior authorization is required for extended-release alpha$_2$ agonists. Payment will be considered for patients when the following is met: 1. The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and 2. Previous trial with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance; and 3. Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant; and The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

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Updated 7/1/2019

Alpha$_1$-Proteinase Inhibitor Enzymes *Use Alpha$_1$-Proteinase Inhibitor EnzymesPA form*	Prior authorization is required for Alpha$_1$-Proteinase Inhibitor enzymes. Payment for a non-preferred Alpha$_1$-Proteinase Inhibitor enzyme will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. Payment will be considered for patients when the following is met: 1. Patient has a diagnosis of congenital alpha$_1$-antitrypsin (AAT) deficiency; with a pretreatment serum concentration of AAT less than 11µM/L or a. 80mg/dl if measured by radial immunodiffusion, or b. 50mg/dl if measured by nephelometry; and 2. Patient has a high-risk AAT deficiency phenotype (PiZZ, PiZ (null), or PI (null)(null) or other phenotypes associated with serum AAT concentrations of less than 11µM/L, such as PiSZ or PiMZ); and 3. Patient has documented progressive panacinar emphysema with a documented rate of decline in forced expiratory volume in 1 second (FEV_1); and 4. Patient is 18 years of age or older; and 5. Patient is currently a non-smoker; and 6. Patient is currently on optimal supportive therapy for obstructive lung disease (inhaled bronchodilators, inhaled steroids); and 7. Medication will be administered in the member's home by home health or in a long-term care facility. If the criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 6 month intervals when the following criteria are met: 1. Evidence of clinical efficacy, as documented by: a. An elevation of AAT levels (above protective threshold i.e., > 11µM/L); and b. A reduction in rate of deterioration of lung function as measured by a decrease in the FEV_1 rate of decline; and 2. Patient continues to be a non-smoker; and 3. Patient continues supportive therapy for obstructive lung disease.
Amylino Mimetic (Symlin®) *Use Amylino Mimetic (Symlin®) form*	Prior authorization is required for amylino mimetics (Symlin®). Payment will be considered under the following conditions: 1. Diagnosis of Type 1 or Type 2 diabetes mellitus, 2. Concurrent use of insulin therapy, 3. Documentation of blood glucose monitoring three or more times daily, 4. Inadequate reduction in HbgA1C despite multiple titration with basal/bolus insulin dosing regiments. Initial authorizations will be approved for six months; additional prior authorizations will be considered on an individual basis after review of medical necessity and documented improvement in HbgA1C since the beginning of the initial prior authorization period.

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Updated 7/1/2019

Antidepressants *Aplenzin* *Fetzima* *Khedezla* *Viibryd* *Use Antidepressants PA form*	Prior authorization is required for non-preferred antidepressants subject to clinical criteria. Requests for doses above the manufacturer recommended dose will not be considered. Payment will be considered for patients when the following criteria are met: 1. The patient has a diagnosis of Major Depressive Disorder (MDD) and is 18 years of age or older; and 2. Documentation of a previous trial and therapy failure at a therapeutic dose with two preferred generic SSRIs; and 3. Documentation of a previous trial and therapy failure at a therapeutic dose with one preferred generic SNRI; and 4. Documentation of a previous trial and therapy failure at a therapeutic dose with one non-SSRI/SNRI generic antidepressant 5. If the request is for an isomer, prodrug or metabolite of a medication indicated for MDD, one of the trials must be with the preferred parent drug of the same chemical entity that resulted in a partial response with a documented intolerance. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
Anti-Diabetics, Non-Insulin Agents *Use Anti-Diabetics, Non-Insulin PA form*	Prior authorization is required for preferred anti-diabetic, non-insulin agents subject to clinical criteria. Payment will be considered under the following conditions: 1. A diagnosis of Type 2 Diabetes Mellitus, and 2. Patient is 18 years of age or older, and 3. The patient has not achieved HgbA1C goals after a minimum three month trial with metformin at maximally tolerated dose. Payment for a non-preferred anti-diabetic, non-insulin agent subject to clinical criteria will be authorized only for cases in which there is documentation of previous trials and therapy failures with metformin, a preferred DPP-4 Inhibitor or DPP-4 Inhibitor Combination, a preferred Incretin Mimetic, and a preferred SGLT2 Inhibitor at maximally tolerated doses. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated. Initial authorizations will be approved for six months. Additional prior authorizations will be considered on an individual basis after review of medical necessity and documented continued improvement in HgbA1C.

Iowa Medicaid Drug Prior Authorization Criteria

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Updated 7/1/2019

Antiemetic-5HT3 Receptor Antagonists/ Substance P Neurokinin Agents *Use Antiemetic-5HT3 Receptor Antagonists/ Substance P Neurokinin Agents form*	Prior authorization is required for preferred Antiemetic-5HT3 Receptor Antagonists/Substance P Neurokinin medications for quantities exceeding the following dosage limits per month. Payment for Antiemetic-5HT3 Receptor Agonists/ Substance P Neurokinin Agents beyond this limit will be considered on an individual basis after review of submitted documentation. Prior authorization will be required for all non-preferred Antiemetic-5HT3 Receptor Antagonists/Substance P Neurokinin medications beginning the first day of therapy. Payment for non-preferred medications will be authorized only for cases in which there is documentation of previous trial(s) and therapy failure with a preferred agent in this class. Note: Aprepitant (Emend) will only be payable when used in combination with other antiemetic agents (5-HT3 medication and dexamethasone) for patients receiving highly emetogenic cancer chemotherapy. Aprepitant (N)/Emend (P): 4 – 125mg capsules 8 – 80mg capsules Dolasetron (N)/Anzemet (N): 5 – 50mg/100mg tablets 4 vials (100mg/5mL) 8 ampules (12.5mg/0.625mL) Granisetron (N): 8 – 1mg tablets 8 vials (1mg/mL) 2 vials (4mg/mL) Akynzeo (N): 2 – 300/0.5mg capsules Ondansetron (P)/Zofran (N): 60 – 4mg tablets 60 – 8mg tablets 4 – 24mg tablets 4 – 20mL vials (2mg/mL) 8 – 2mL vials (2mg/mL) Ondansetron ODT (P)/Zofran ODT (N): 60 – 4mg tablets 60 – 8mg tablets Ondansetron Oral Solution (N)/ Zofran Oral Solution (N) 50mL/month – oral solution (4mg/5mL) Palonosetron (N)/ Aloxi (N): 4 vials (0.25mg/5mL)
Anti-Fungal- Oral / Injectable *Use Anti-Fungal PA form*	Prior authorization is not required for preferred antifungal therapy for a cumulative 90 days of therapy per 12-month period per patient. Prior authorization will be required for all non-preferred antifungal therapy beginning the first day of therapy. Payment for a non-preferred antifungal will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. Payment for any antifungal therapy beyond a cumulative 90 days of therapy per 12-month period per patient will be authorized in cases where the patient has a diagnosis of an immunocompromised condition or a systemic fungal infection. This prior authorization requirement does not apply to nystatin.
Antihistamines *Use Antihistamine PA form*	Prior authorization is required for all non-preferred oral antihistamines. Patients 21 years of age and older must have three unsuccessful trials with antihistamines that do not require prior authorization, prior to the approval of a non-preferred oral antihistamine. Two of the trials must be with cetirizine and loratadine. Patients 20 years of age and younger must have unsuccessful trials with cetirizine and loratadine prior to the approval of a non-preferred oral antihistamine. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

For all drugs requiring prior authorization, in the event of an emergency situation when a prior authorization request cannot be submitted and a response received within 24 hours such as after regular working hours or on weekends, a 72-hour supply of the drug may be dispensed and reimbursement will be made, unless otherwise noted in criteria. Certain drugs are allowed a 7 day supply while prior authorization is being requested. PDL IMPLEMENTATION DATE 01-15-05

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Apremilast (Otezla®)	Prior authorization is required for apremilast (Otezla®). Payment will be considered under the following conditions: 1. Patient is 18 years of age or older; and 2. Patient has a diagnosis of active psoriatic arthritis (≥ 3 swollen joints and ≥ 3 tender joints); or 3. Patient has a diagnosis of moderate to severe plaque psoriasis; and 4. Patient does not have severe renal impairment (CrCl < 30 mL/min). <u>Psoriatic Arthritis</u> 1. Patient has documentation of a trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and 2. Patient has documentation of trials and therapy failures with two preferred biological agents indicated for psoriatic arthritis. <u>Plaque Psoriasis</u> 1. Patient has documentation of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine; and 2. Patient has documentation of trials and therapy failures with two preferred biological agents indicated for plaque psoriasis. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
Becaplermin (Regranex®) *Use Regranex® PA form*	Prior authorization is required for Regranex®. Payment for new prescriptions will be authorized for ten weeks for patients who meet the following criteria: 1. Diagnosis of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond 2. Inadequate response to 2 weeks of wound debridement and topical moist wound dressing Longer than 10 weeks will be authorized for patients who meet the following criteria: 1. Wound has decreased in size by 30% after 10 weeks
Benzodiazepines *Use Benzodiazepine PA form*	Prior authorization is required for non-preferred benzodiazepines. Payment for non-preferred benzodiazepines will be authorized in cases with documentation of previous trial and therapy failure with two preferred products. Requests for clobazam (ONFI) will be considered for a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older when used as an adjunctive treatment. Prior authorization will be approved for up to 12 months for documented: 1. Generalized anxiety disorder. 2. Panic attack with or without agoraphobia. 3. Seizure. 4. Non-progressive motor disorder. 5. Dystonia. If a long-acting medication is requested, one of the therapeutic trials must include the immediate release form of the requested benzodiazepine. Prior authorization requests will be approved for up to a three-month period for all other diagnoses related to the use of benzodiazepines. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

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Updated 7/1/2019

Biologicals for Ankylosing Spondylitis *Adalimumab (Humira)* *Certolizumab Pegol (Cimzia)* *Etanercept (Enbrel)* *Golimumab (Simponi)* *Secukinumab (Cosentyx)* *Use Biologicals for Ankylosing Spondylitis PA form*	Prior authorization is required for biologicals used for ankylosing spondylitis. Request must adhere to all FDA approved labeling. Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions: 1. Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and 2. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and 3. Patient has documentation of an inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration; and 4. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include sulfasalazine and methotrexate. In addition to the above: Requests for TNF Inhibitors: 1. Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and 2. Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less. Requests for Interleukins: 1. Medication will not be given concurrently with live vaccines. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Iowa Medicaid Drug Prior Authorization Criteria

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Updated 7/1/2019

Biologicals for Arthritis *Abatacept (Orencia)* *Adalimumab (Humira)* *Anakinra (Kineret)* *Certolizumab Pegol (Cimzia)* *Etanercept (Enbrel)* *Ixekizumab (Taltz)* *Golimumab (Simponi)* *Tocilizumab (Actemra)* *Ustekinumab (Stelara)* *Canakinumab (Ilaris)* *Sarilumab (Kevzara)* *Secukinumab (Cosentyx)* *Use Biologicals for Arthritis PA form*	Prior authorization is required for biologicals used for arthritis. Request must adhere to all FDA approved labeling. Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions: 1. Patient has been screened for hepatitis B and C. Patients with evidence of active hepatitis B infection (hepatitis surface antigen positive > 6 months) must have documentation they are receiving or have received effective antiviral treatment; and 2. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and 3. Patient has a diagnosis of rheumatoid arthritis (RA): A trial and inadequate response to two preferred disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxycholoroquine, sulfasalazine, or leflunomide). Upon an unsuccessful methotrexate trial in patients with established RA, the combination trial with a second DMARD may be overridden if there is evidence of severe disease documented by radiographic erosions; or 1. Patient has a diagnosis of moderate to severe psoriatic arthritis: A trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or 2. Patient has a diagnosis of moderate to severe juvenile idiopathic arthritis: A trial and inadequate response to intraarticular glucocorticoid injections and the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and In addition to the above: Requests for TNF Inhibitors: 1. Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and 2. Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less. Requests for Interleukins: 1. Medication will not be given concurrently with live vaccines. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

For all drugs requiring prior authorization, in the event of an emergency situation when a prior authorization request cannot be submitted and a response received within 24 hours such as after regular working hours or on weekends, a 72-hour supply of the drug may be dispensed and reimbursement will be made, unless otherwise noted in criteria. Certain drugs are allowed a 7 day supply while prior authorization is being requested. PDL IMPLEMENTATION DATE 01-15-05

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Updated 7/1/2019

Biologicals for Inflammatory Bowel Disease *Adalimumab (Humira)* *Certolizumab Pegol (Cimzia)* *Golimumab (Simponi)* *Ustekinumab (Stelara)* *Use Biologicals for Inflammatory Bowel Disease PA form*	Prior authorization is required for biologicals used for inflammatory bowel disease. Request must adhere to all FDA approved labeling. Payment for non-preferred biologicals for inflammatory bowel disease will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions: 1. Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and 2. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and 3. Patient has a diagnosis of Crohn's Disease – Payment will be considered following an inadequate response to two preferred conventional therapy including aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate; or 4. Patient has a diagnosis of Ulcerative Colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine; and In addition to the above: Requests for TNF Inhibitors: 1. Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and 2. Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less; and Requests for Interleukins: 1. Medication will not be given concurrently with live vaccines. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

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Updated 7/1/2019

Biologicals for Hidradenitis Suppurativa *Adalimumab (Humira)* *Use Biologicals for Hidradenitis Suppurativa PA form*	Prior authorization is required for biologicals FDA approved for the treatment of Hidradenitis Suppurativa (HS). Patients initiating therapy with a biological agent must: 1. Be screened for hepatitis B and C. Patients with active hepatitis B will not be considered for coverage; and 2. Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biologic agent; and 3. Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and 4. Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment. Payment will be considered under the following conditions: 1. Patient has a diagnosis of moderate to severe HS with Hurley Stage II or III disease; and 2. Patient is 18 years of age or older; and 3. Patient has at least three (3) abscesses or inflammatory nodules; and 4. Patient has documentation of adequate trials and therapy failures with the following: a. Daily treatment with topical clindamycin; b. Oral clindamycin plus rifampin; c. Maintenance therapy with tetracyclines (doxycycline or minocycline). If criteria for coverage are met, initial requests will be given for 3 months. Additional authorizations will be considered upon documentation of clinical response to therapy. Clinical response is defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count from initiation of therapy. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

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Updated 7/1/2019

Biologicals for Plaque Psoriasis *Adalimumab (Humira)* *Etanercept (Enbrel)* *Secukinumab (Cosentyx)* *Ustekinumab (Stelara)* *Brodalumab (Siliq)* *Ixekizumab (Taltz)* *Guselkumab (Tremfya)* *Use Biologicals for Plaque Psoriasis PA form*	Prior authorization is required for biologicals used for plaque psoriasis. Request must adhere to all FDA approved labeling. Payment for non-preferred biologicals for plaque psoriasis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions: 1. Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and 2. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and 3. Patient has documentation of an inadequate response to phototherapy, systemic retinoids (oral isotretinoin), methotrexate, or cyclosporine; and In addition to the above: Requests for TNF Inhibitors 1. Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and 2. Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less. Requests for Interleukins: 1. Medication will not be given concurrently with live vaccines. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

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Updated 7/1/2019

Buprenorphine/ Naloxone *Use Buprenorphine/ Naloxone PA form*	Prior authorization(PA) is required for transmucosal buprenorphine or buprenorphine/naloxone. Requests will be considered for FDA approved dosing, including induction and maintenance dose. Requests for doses above 24mg per day will not be considered. Initial requests will be considered for up to 3 months. Requests for maintenance doses above 16mg per day will not be considered on a long-term basis. After the initial 3 month PA, renewal requests for doses ≤ 16mg per day may be considered for 12 month renewals as long as the member meets all other PA criteria. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. Requests for surgically implanted buprenorphine or buprenorphine depot injection products will not be considered through the pharmacy benefit and should be directed to the member's medical benefit. Payment will be considered for patients when the following is met: 1. Patient has a diagnosis of opioid dependence and meets the FDA approved age: AND 2. Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number (provide X DEA number); AND 3. Documentation the Iowa Prescription Monitoring Program (PMP) website has been reviewed for the patient's use of controlled substances; AND 4. Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant or depot injection. 5. Requests for single ingredient buprenorphine will only be considered for pregnant patients. Requests for renewal must include: 1. Documentation the Iowa PMP website has been reviewed for the patient's use of controlled substances since the last prior authorization request, AND 2. Patient does not have documentation of concomitant use of an opioid or tramadol with the requested buprenorphine product, as seen in paid pharmacy claims, AND 3. Patient is not using transmucosal buprenorphine with buprenorphine implant or depot injection.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Calcifediol (Rayaldee) *Use Calcifediol (Rayaldee) PA form*	Prior authorization is required for calcifediol (Rayaldee). Initial requests will be considered for patients when the following criteria are met: 1. Patient is 18 years of age or older; and 2. Patient is being treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) as documented by a current glomerular filtration rate (GFR); and 3. Patient is not on dialysis; and 4. Patient has a serum total 25-hydroxyvitamin D level less than 30 ng/mL and a serum corrected total calcium below 9.8 mg/dL within the past 3 months; and 5. Patient has documentation of a previous trial and therapy failure at a therapeutic dose with a preferred vitamin D analog for a minimum of 3 months. 6. Initial requests will be considered for a dose of 30 mcg once daily for 3 months. Continuation of therapy will be considered when the following criteria are met: 1. Patient continues to need to be treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) documented by a current glomerular filtration rate (GFR); and 2. Patient has a serum total 25-hydroxyvitamin D level between 30 and 100 ng/mL, a serum corrected total calcium below 9.8 mg/dL, and a serum phosphorus below 5.5 mg/dL.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

CGRP Inhibitors *Use CGRP Inhibitors PA form*	Prior authorization is required for CGRP Inhibitors. Payment will be considered for patients when the following is met: 1. Patient has a diagnosis of migraine as defined by one of the following: a. Chronic Migraine i. ≥ 15 headache days per month for a minimum of 3 months; and ii. ≥ 8 migraine headaches days per month for a minimum of 3 months; or b. Episodic Migraine i. 4 to 14 migraine days per month for a minimum of 3 months; and 2. Patient meets the FDA approved age; and 3. Patient has been evaluated for and does not have medication overuse headache; and 4. Patient has documentation of three trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with a minimum of two different migraine prophylaxis drug classes (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); and 5. The requested dose does not exceed the maximum FDA labeled dose; and 6. Lost, stolen, or destroyed medication replacement requests will not be authorized. Initial requests will be approved for 3 months. Additional prior authorizations will be considered upon documentation of clinical response to therapy (i.e., reduced migraine frequency, reduced migraine headache days). The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Cholic Acid (Cholbam®) *Use Cholic Acid (Cholbam®) PA form*	Prior authorization is required for cholic acid (Cholbam). Payment will be considered under the following conditions: 1. Is prescribed by a hepatologist or pediatric gastroenterologist; and 2. Is prescribed for a diagnosis of bile acid synthesis disorder due to a single enzyme defect (SED) including: a. 3-beta-hydroxy-delta-5C27-steroid oxidoreductase deficiency (3β-HSD), b. aldo-keto reductase 1D1 (AKR1D1), c. alpha-methylacyl-CoA racemase deficiency (AMACR deficiency), d. sterol 27-hydroxylase deficiency (cerebrotendinous xanthomatosis [CTX]), e. cytochrome P450 7A1 (CYP7A1), f. 25-hydroxylation pathway (Smith-Lemli-Opitz); OR 3. Is prescribed as an adjunctive treatment of a peroxisomal disorder (PD) in patients who exhibit manifestations of liver disease, steatorrhea, or complications from fat soluble vitamin absorption. Peroxisomal disorders include Zellweger syndrome (ZWS), neonatal adrenoleukodystrophy (NALD), or infantile refsum disease (IRD); and 4. Diagnosis is confirmed by mass spectrometry or other biochemical testing or genetic testing (attach results); and 5. Baseline liver function tests are taken prior to initiation of therapy (AST, ALT, GGT, ALP, total bilirubin, INR) and provided with request; and 6. Patient must have elevated serum aminotransferases (AST and ALT) with normal serum gamma glutamyltransferase (GTT); and 7. Patient is at least 3 weeks old. When criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 12 months at a time requiring documentation of response to therapy by meeting two of the following criteria: 1. Body weight has increased by 10% or is stable at ≥50th percentile, 2. Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 50 U/L or baseline levels reduced by 80%, 3. Total bilirubin level reduced to ≤1mg/dL.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Chronic Pain Syndromes ***Duloxetine (Cymbalta®)*** ***Pregabalin (Lyrica®)*** ***Milnacipran (Savella™)*** *Use Chronic Pain Syndromes PA form*	A prior authorization is required for pregabalin (Lyrica®) and milnacipran (Savella™). These drugs will be considered for their FDA indications(s) and other conditions as listed in the compendia. Requests for doses above the manufacturer recommended dose will not be considered. For patients with a chronic pain diagnosis who are currently taking opioids, as seen in pharmacy claims, a plan to decrease and/or discontinue the opioid(s) must be provided with the initial request. Initial authorization will be given for three (3) months. Requests for renewal must include an updated opioid treatment plan and documentation of improvement in symptoms and quality of life. Requests for non-preferred brand name drugs, when there is a preferred A-rated bioequivalent generic product available, are also subject to the Selected Brand Name prior authorization criteria and must be included with this request. Payment will be considered under the following conditions: 1. A diagnosis of fibromyalgia (Lyrica® and Savella™) a. a trial and therapy failure at a therapeutic dose with gabapentin plus one of the following preferred generic agents: tricyclic antidepressant or SNRI **WITH** b. documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.) 2. A diagnosis of post-herpetic neuralgia (Lyrica®) A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, topical lidocaine, or valproate. 3. A diagnosis of diabetic peripheral neuropathy (duloxetine and Lyrica®) A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant or duloxetine. 4. A diagnosis of partial onset seizures, as adjunct therapy (Lyrica®) 5. A diagnosis of neuropathic pain associated with spinal cord injury (Lyrica®)
CNS Stimulants and Atomoxetine	Prior authorization (PA) is required for CNS stimulants and atomoxetine for patients 21 years of age or older. Prior to requesting prior authorization for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website. Requests will be considered for an FDA approved age for the submitted diagnosis. Payment for CNS stimulants and atomoextine will be considered under the following conditions: 1. Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational). Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD. Adults (≥ 21 years of age) are limited to the use of long-acting agents only. If supplemental dose with a short-acting agent is needed for an adult in the mid to late afternoon, requests will be considered under the following circumstances: the dose of the long-acting agent has been optimized, documentation is provided a short-acting agent of the same chemical entity is medically necessary (e.g. employed during the day with school in the evening, and will be limited to one unit dose per day. Children (< 21 years of age) are limited to the use of long-acting agents with one unit of a short acting agent per day. 2. Narcolepsy with diagnosis confirmed with a recent sleep study (ESS, MSLT, PSG). 3. Excessive sleepiness from obstructive sleep apnea/hypopnea syndrome (OSAHS) with documentation of non-pharmacological therapies tried (weight loss, position therapy, CPAP at maximum titration, BiPAP at maximum titration or surgery) and results from a recent sleep study (ESS, MSLT, PSG) with the diagnosis confirmed by a sleep specialist. 4. Binge Eating Disorder (Vyvanse only)

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Use CNS Stimulants and Atomoxetine or Binge Eating Disorder Agents PA form	a. Patient is 18 to 55 years of age; and b. Patient meets DSM-5 criteria for Binge Eating Disorder (BED); and c. Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number of episodes must be reported); and d. Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent 3 month period, that did not significantly reduce the number of binge eating episodes; and e. Prescription is written by a psychiatrist or psychiatric nurse practitioner; and f. Patient has a BMI of 25 to 45; and g. Patient does not have a history of cardiovascular disease; and h. Patient has no history of substance abuse; and i. Is not being prescribed for the treatment of obesity or weight loss; and j. Doses above 70mg per day will not be considered. k. Initial requests will be approved for 12 weeks. l. Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week. <u>DSM-5 Criteria</u> i. Recurrent episodes of binge eating, including eating an abnormally large amount of food in a discrete period of time and has a feeling of lack of control over eating; and ii. The binge eating episodes are marked by at least three of the following: 1. Eating more rapidly than normal 2. Eating until feeling uncomfortably full 3. Eating large amounts of food when not feeling physically hungry 4. Eating alone because of embarrassment by the amount of food consumed 5. Feeling disgusted with oneself, depressed, or guilty after overeating; and iii. Episodes occur at least 1 day a week for at least 3 months; and iv. No regular use of inappropriate compensatory behaviors (e.g. purging, fasting, or excessive exercise) as are seen in bulimia nervosa; and v. Does not occur solely during the course of bulimia nervosa or anorexia nervosa. <u>Moderate to Severe BED</u> Based on the number of binge eating episodes per week: Moderate - 4 to 7 Severe – 8 to 13 Extreme – 14 or more Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *If a non-preferred long-acting medication is requested, a trial with the preferred extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Concurrent IM/PO Antipsychotic Use *Use Concurrent IM/PO Antipsychotic Utilization PA form*	A prior authorization is required for concurrent long acting injectable and oral antipsychotic medications after 12 weeks (84 days) of concomitant treatment for members 18 years of age and older. Consideration of concomitant therapy beyond 12 weeks (84 days) will require documentation of medical necessity. Prior authorization is required for all non-preferred antipsychotics as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for non-preferred antipsychotics will be considered only for cases in which there is documentation of previous trials and therapy failures with a preferred agent.
Crisaborole (Eucrisa) *Use Crisaborole (Eucrisa) PA form*	Prior authorization is required for Eucrisa (crisaborole). Payment will be considered for patients when the following criteria are met: 1. Patient has a diagnosis of mild to moderate atopic dermatitis; and 2. Patient is within the FDA labeled age; and 3. Patient has failed to respond to good skin care and regular use of emollients; and 4. Patient has documentation of an adequate trial and therapy failure with two preferred medium to high potency topical corticosteroids for a minimum of 2 consecutive weeks; and 5. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and 6. Patient will continue with skin care regimen and regular use of emollients. 7. Quantities will be limited to 60 grams for use on the face, neck, and groin and 100 grams for all other areas, per 30 days. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.
Dalfampridine (Ampyra™) *Use Dalfampridine (Ampyra™) PA form*	Prior authorization is required for dalfampridine (Ampyra™). Payment will be considered under the following conditions: 1. For patients that have a gait disorder associated with MS. 2. Initial authorizations will be approved for 12 weeks with a baseline Timed 25-foot Walk (T25FW) assessment. 3. Additional prior authorizations will be considered at 6 month intervals after assessing the benefit to the patient as measured by a 20% improvement in the T25FW from baseline. Renewal will not be approved if the 20% improvement is not maintained. Prior authorizations will not be considered for patients with a seizure diagnosis or in patients will moderate to severe renal impairment.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Deferasirox (Exjade®) *Use Deferasirox (Exjade®) PA form*	Prior authorization is required for deferasirox. Requests will only be considered for FDA approved dosing. Payment will be considered under the following conditions: 1. Patient does not have a serum creatinine greater than 2 times the age-appropriate upper limit of normal or creatinine clearance <40mL/min; and 2. Patient does not have a poor performance status; and 3. Patient does not have a high-risk myelodysplastic syndrome; and 4. Patient does not have advanced malignancies; and 5. Patient does not have a platelet count < 50 x 10^9/L. **Transfusional Iron Overload** Initiation of Therapy 1. Patient is 2 years of age or older; and 2. Patient has documentation of iron overload related to anemia (attach documentation); and 3. Patient has documentation of a recent history of frequent blood transfusions that has resulted in chronic iron overlaod; and 4. Serum ferritin is consistently > 1000 mcg/L (attach lab results dates within the past month); and 5. Starting dose does not exceed: Exjade- 20mg/kg/day or Jadenu- 14mg/kg/day. Calculate dose to the nearest whole tablet. 6. Initial requests will be considered for up to 3 months. Continuation of Therapy 1. Serum ferritin has been measured within 30 days of continuation of therapy request (attach documentation); and 2. Ferritin levels are > 500mcg/L; and 3. Dose does not exceed: Exjade- 40mg/kg/day or Jadenu- 28mg/kg/day. **Non-Transfusional Iron Overload** Initiation of Therapy 1. Patient is 10 years of age or older; and 2. Patient has documentation of iron overload related to anemia (attach documentation); and 3. Serum ferritin and liver iron concentration (LIC) has been measured within 30 days of initiation (attach lab results); and 4. Serum ferritin levels are > 300mcg/L; and 5. LIC are > 5mg Fe/g dw; and 6. Dose does not exceed: Exjade- 10mg/kg/day (if LIC is ≤ 15mg Fe/g dw), or 20mg/kg/day (if LIC is > 15mg Fe/g dw) or Jadenu- 7mg/kg/day (if LIC is ≤ 15mg Fe/g dw), or 14mg/kg/day (if LIC is > 15mg Fe/g dw). 7. Initial authorization will be considered for up to 6 months. Continuation of Therapy 1. Serum ferritin and LIC have been measured within 30 days of continuation of therapy request; and 2. Serum ferritin levels are ≥ 300mcg/L; and 3. LIC is ≥ 3mg Fe/g dw; and 4. Dose does not exceed: Exjade- 10mg/kg/day (if LIC is 3 to 7 mg Fe/g dw) or 20mg/kg/day (if LIC is > 7mg Fe/g dw) or Jadenu- 10mg/kg/day (if LIC is 3 to 7 mg Fe/g dw) or 20mg/kg/day (if LIC is > 7mg Fe/g dw).

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Deflazacort (Emflaza) *Use Deflazacort (Emflaza™) PA form*	Prior authorization is required for Emflaza (deflazacort). Payment will be considered for patients when the following criteria are met: 1. Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with documented mutation of the dystrophin gene; and 2. Patient is within the FDA labeled age; and 3. Patient experienced onset of weakness before 5 years of age; and 4. Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and 5. Patient has documentation of an adequate trial and therapy failure, intolerance, or significant weight gain (significant weight gain defined as 1 standard deviation above baseline percentile rank weight for height) while on prednisone at a therapeutic dose; and 6. Is dosed based on FDA approved dosing. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.
Dextromethorphan and Quinidine (Nuedexta™) *Use Dextromethorphan and Quinidine (Nuedexta™) PA form*	Prior authorization is required for Nuedexta™. Payment will be considered under the following conditions: 1. Patients must have a diagnosis of pseudobulbar affect (PBA) secondary to a neurological condition. 2. A trial and therapy failure at a therapeutic dose with amitriptyline or an SSRI; and 3. Patient has documentation of a current EKG (within the past 3 months) without QT prolongation. 4. Initial authorizations will be approved for 12 weeks with a baseline Center for Neurologic Studies Lability Scale (CNS-LS) questionnaire. 5. Subsequent prior authorizations will be considered at 6 month intervals with documented efficacy as seen in an improvement in the CNS-LS questionnaire. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.
Dornase Alfa (Pulmozyme®) *Use Miscellaneous PA form*	Prior authorization is required for Pulmozyme®. Payment will be authorized only for cases in which there is a diagnosis of cystic fibrosis.
Duloxetine (Cymbalta®) *Use Chronic Pain Syndromes PA form*	*See Chronic Pain Syndromes Prior Authorization Criteria.*

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Dupilumab (Dupixent) *Use Dupilumab (Dupixent) PA form*	Prior authorization is required for Dupixent (dupilumab). Payment will be considered for patients when the following criteria are met: 1. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and 2. Patient is within the FDA labeled age; and 3. Is prescribed by or in consultation with a dermatologist; and 4. Patient has failed to respond to good skin care and regular use of emollients; and 5. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and 6. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and 7. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and 8. Patient will continue with skin care regimen and regular use of emollients; and 9. Dose does not exceed an initial one-time dose of 600mg and maintenance dose of 300mg thereafter given every other week. If criteria for coverage are met, initial authorization will be given for 16 weeks to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.
Duplicate Therapy Edits **Antipsychotics** **NSAIDs** *Use Duplicate Therapy Edit Override PA form*	Designated therapeutic classes are subject to duplicate therapy edits. Providers should submit a Prior Authorization request for override consideration.
Elagolix (Orilissa) *Use Elagolix (Orilissa) PA form*	Prior authorization is required for gonadotropin-releasing hormone (GnRH) antagonists. Payment will be considered for patients when the following is met: 1. Patient has a diagnosis of moderate to severe pain associated with endometriosis; and 2. Pregnancy has been ruled out; and 3. Patient does not have osteoporosis; and 4. Patient does not have severe hepatic impairment; and 5. Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g. cyclosporine and gemfibrozil); and 6. Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and 7. Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist. 8. Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose. Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Eluxadoline (Viberzi™) *Use Eluxadoline (Viberzi™) PA form*	Prior authorization is required for eluxadoline. Only FDA approved dosing will be considered. Payment will be considered under the following conditions: 1. Patient is 18 years of age or older. 2. Patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D). 3. Patient does not have any of the following contraindications to therapy: a. Patient is without a gallbladder. b. Known or suspected biliary duct obstruction, or sphincter of Oddi disease/dysfunction. c. Alcoholism, alcohol abuse, alcohol addiction, or consumption of more than 3 alcoholic beverages per day. d. A history of pancreatitis or structural diseases of the pancreas (including known or suspected pancreatic duct obstruction). e. Severe hepatic impairment (Child-Pugh Class C). f. Severe constipation or sequelae from constipation. g. Known or suspected mechanical gastrointestinal obstruction. 4. Patient has documentation of a previous trial and therapy failure at a therapeutic dose with both of the following: a. A preferred antispasmodic agent (dicyclomine or hyoscyamine). b. A preferred antidiarrheal agent (loperamide). If criteria for coverage are met, initial authorization will be given for 3 months to assess the response to treatment. Requests for continuation of therapy will require the following: 1. Patient has not developed any contraindications to therapy (defined above). 2. Patient has experienced a positive clinical response to therapy as demonstrated by at least one of the following: a. Improvement in abdominal cramping or pain. b. Improvement in stool frequency and consistency. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
Eplerenone (Inspra®) *Use Miscellaneous PA form*	Prior authorization is required for Inspra®. Payment will be authorized only in cases where there is documented trial and therapy failure on Aldactone® or documented cases of gynecomastia from Aldactone® therapy.

Iowa Medicaid Drug Prior Authorization Criteria

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Erythropoiesis Stimulating Agents *Use Erythropoesis Stimulating Agent PA form*	Prior authorization is required for erythropoiesis stimulating agents prescribed for outpatients for the treatment of anemia. Payment for non-preferred erythropoiesis stimulating agents will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. Patients who meet all of the following criteria may receive prior authorization for the use of erythropoiesis stimulating agents: 1. Hemoglobin less than 10g/dL.If renewal of prior authorization is being requested, a hemoglobin less than 11g/dL (or less than 10g/dL for patients with Chronic Kidney Disease (CKD) not on dialysis) will be required for continued treatment.Hemoglobin laboratory values must be dated within four weeks of the prior authorization request. 2. Transferrin saturation greater than or equal to 20 percent (transferrin saturation is calculated by dividing serum iron by the total iron binding capacity), ferritin levels greater than or equal to 100 mg/ml, or on concurrent therapeutic iron therapy. Transferrin saturation or ferritin levels must be dated within three months of the prior authorization request. 3. For HIV-infected patients, the endogenous serum erythropoietin level must be less than or equal to 500 mU/ml to initiate therapy. 4. No evidence of untreated GI bleeding, hemolysis, or Vitamin B-12, iron or folate deficiency.
Extended Release Formulations *Use Extended Release Formulations PA form*	Payment for a non-preferred extended release formulation will be considered when the following criteria are met: 1. Previous trial and therapy failure with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance and 2. Previous trial and therapy failure at a therapeutic dose with a preferred drug of a different chemical entity indicated to treat the submitted diagnosis. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated. Prior authorization is required for the following extended release formulation(s): Adoxa, Amoxicillin ER, Astagraf XL, Augmentin XR, Cardura XL, Carvedilol ER, Cipro XR, Coreg CR, Doryx, Envarsus XR, Fortamet, Glumetza, Gocovri, Gralise, Kapspargo, Keppra XR, Lamictal XR, Luvox CR, Memantine ER, Mirapex ER, Moxatag, Namenda XR, Oleptro, Osmolex ER, Oxtellar XR, Pramipexole ER, Prozac Weekly, Qudexy XR, Rayos, Requip XL, Rythmol SR, Solodyn ER, Topiramate ER, Trokendi XR, Ximino.
Febuxostat (Uloric®) *Use Febuxostat (Uloric®) PA form*	Prior authorization is required for febuxostat (Uloric®). Payment for febuxostat (Uloric®) will only be considered for cases in which symptoms of gout still persist while currently using 300mg per day of a preferred allopurinol product unless documentation is provided that such a trial would be medically contraindicated.
Fentanyl, Short Acting Products *Use Short Acting Fentanyl Products PA form*	Prior authorization is required for short acting fentanyl products. Payment will be considered only if the diagnosis is for breakthrough cancer pain in opioid tolerant patients. These products carry a **Black Box Warning**. Short acting fentanyl products: 1. Are indicated only for the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying persistent cancer pain. 2. Are contraindicated in the management of acute or postoperative pain. Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, do not use in opioid non-tolerant patients.

For all drugs requiring prior authorization, in the event of an emergency situation when a prior authorization request cannot be submitted and a response received within 24 hours such as after regular working hours or on weekends, a 72-hour supply of the drug may be dispensed and reimbursement will be made, unless otherwise noted in criteria. Certain drugs are allowed a 7 day supply while prior authorization is being requested. PDL IMPLEMENTATION DATE 01-15-05

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Fifteen Day Initial Prescription Supply Limit *Use Fifteen Day Initial Prescription Supply Limit PA form*	Designated drugs are limited to a fifteen day initial supply. These drugs are identified on the Fifteen Day Initial Prescription Supply Limit list located on the website www.iowamedicaidpdl.com under the Preferred Drug Lists tab. Providers must submit a prior authorization request for override consideration. Documentation of medical necessity, excluding patient convenience, is required for consideration of the fifteen day initial supply override.
GLP-1 Agonist/Basal Insulin Combinations *Use GLP-1 Agonist/Basal Insulin Combinations PA form*	Prior authorization is required for GLP-1 agonist receptor/basal insulin combination products. Payment will be considered for patients when the following criteria are met: 1. A diagnosis of type 2 diabetes mellitus; and 2. Patient is 18 years of age or older; and 3. The patient has not achieved HgbA1C goals after a minimum three-month trial with metformin at a maximally tolerated dose, unless evidence is provided that use of this agent would be medically contraindicated; and 4. Documentation of an adequate trial and inadequate response with at least one preferred GLP-1 receptor agonist and one preferred long-acting insulin agent concurrently; and 5. Will not be used concurrently with prandial insulin; and 6. Clinical rational is provided as to why the patient cannot use a preferred GLP-1 receptor agonist and a preferred long-acting insulin agent concurrently; and 7. Medication will be discontinued and alternative antidiabetic products will be used if patients require a daily dosage of: a. Soliqua below 15 units or over 60 units, or b. Xultophy persistently below 16 units or over 50 units.
Granulocyte Colony Stimulating Factor Agents *Use Granulocyte Colony Stimulating Factor PA form*	Prior authorization is required for therapy with granulocyte colony stimulating factor agents. Payment for non-preferred granulocyte colony stimulating factor agents will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. Laboratory values for complete blood and platelet count must be obtained as directed by the manufacturer's instructions. Dosage reduction and discontinuation of therapy may be required based on the manufacturer's guidelines. Payment shall be authorized for one of the following uses: 1. Prevention or treatment of febrile neutropenia in patients with malignancies who are receiving myelosuppressive anticancer therapy. 2. Treatment of neutropenia in patients with malignancies undergoing myeloablative chemotherapy followed by bone marrow transplant. 3. Mobilization of progenitor cells into the peripheral blood stream for leukapheresis collection to be used after myeloablative chemotherapy. 4. Treatment of congenital, cyclic, or idiopathic neutropenia in symptomatic patients. 5. On current chemotherapy drug(s) that would cause severe neutropenia.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Growth Hormone *Use Growth Hormone PA form*	Prior authorization is required for therapy with growth hormones. Payment for non-preferred growth hormones will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. All of the following criteria must be met for approval for prescribing of growth hormones: 1. Standard deviation of 2.0 or more below mean height for chronological age. 2. No intracranial lesion or tumor diagnosed by MRI. 3. Growth rate below five centimeters per year. 4. Failure of any two stimuli tests to raise the serum growth hormone level above ten nanograms per milliliter. Stimuli testing will not be required for the following diagnoses: Turners Syndrome, chronic renal failure, and HIV/AIDS. 5. Annual bone age testing is required for the diagnosis of Growth Hormone Deficiency. A Bone age 14 to 15 years or less in females and 15 to 16 years or less in males is required. 6. Epiphyses open. Prior authorization will be granted for 12-month periods per patient as needed. The following FDA approved indications for Growth Hormone therapy are considered not medically necessary and requests will be denied: Idiopathic Short Stature (ISS) and Small for Gestational Age (SGA). If the request is for **Zorbtive**® [somatropin (rDNA origin) for injection] approval will be granted for the treatment of Short Bowel Syndrome in patients receiving specialized nutritional support. Zorbtive® therapy should be used in conjunction with optimal management of Short Bowel Syndrome.
Hematopoietics/ Chronic ITP *Use Hematopoietics/Chronic ITP PA form*	Prior authorization is required for hematopoietics/chronic ITP agents. Request must adhere to all FDA approved labeling. Payment for a non-preferred hematopoietic/chronic ITP agent will be considered following documentation of a recent trial and therapy failure with a preferred hematopoietic/ITP agent, when applicable, unless such a trial would be medically contraindicated. Payment will be considered under the following conditions: 1. A diagnosis of thrombocytopenia with chronic immune thrombocytopenia (ITP) (Promacta, Nplate, Tavalisse) a. Patient has documentation of an insufficient response to a corticosteroid, immunoglobulin, or splenectomy. 2. A diagnosis of severe aplastic anemia (Promacta) a. Patient has documentation of an insufficient response or intolerance to at least one prior immunosuppressive therapy; and b. Patient has a platelet count less than or equal 30 x 10^9/L. c. If criteria for coverage are met, initial authorization will be given for 16 weeks. Documentation of hematologic response after 16 weeks of therapy will be required for further consideration. 3. A diagnosis of thrombocytopenia with chronic liver disease in patients who are scheduled to undergo a procedure with the following documentation (Doptelet, Mulpleta): a. Pre-treatment platelet count; and b. Scheduled dosing prior to procedure; and c. Therapy completion prior to scheduled procedure; and d. Platelet count will be obtained before procedure.

For all drugs requiring prior authorization, in the event of an emergency situation when a prior authorization request cannot be submitted and a response received within 24 hours such as after regular working hours or on weekends, a 72-hour supply of the drug may be dispensed and reimbursement will be made, unless otherwise noted in criteria. Certain drugs are allowed a 7 day supply while prior authorization is being requested. PDL IMPLEMENTATION DATE 01-15-05

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Hepatitis C Treatments	Prior authorization is required for hepatitis C treatments. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions: 1. Patient has a diagnosis of chronic hepatitis C; and 2. Patient's age and/or weight is within the FDA labeled age and/or weight; and 3. Patient has had testing for hepatitis C virus (HCV) genotype; and 4. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and 5. Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and 6. Patient has advanced liver disease corresponding to a Metavir score of 2 or greater fibrosis as confirmed by one of the following: a. Liver biopsy confirming Metavir score ≥ F2; or b. Transient elastography (FibroScan) score ≥ 7.5kPa; or c. FibroSURE (FibroTest) score ≥ 0.48; or d. APRI score > 0.7; or e. Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); or f. Physical findings or clinical evidence consistent with cirrhosis; or g. Patients at highest risk for severe complications: organ transplant, type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), proteinuria, nephritic syndrome, or membranoproliferative glomerulonephritis. 7. Patient's prior treatment history is provided (treatment naïve or treatment experienced); and 8. If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and 9. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and 10. For regimens containing sofosbuvir, patient does not have severe renal impairment (creatinine clearance < 30ml/min) or end stage renal disease requiring hemodialysis; and 11. HCV treatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and. 12. For patients on a regimen containing ribavirin, the following must be documented on the PA form: a. Patient is not a pregnant female or male with a pregnant female partner; and b. Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and c. Monthly pregnancy tests will be performed during treatment; and 13. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication. 14. Documentation is provided for patients who are ineligible to receive ribavirin. 15. Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved. 16. Patient does not have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.

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Updated 7/1/2019

Use Hepatitis C Treatments PA form	17. If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment. 18. Lost or stolen medication replacement requests will not be authorized. 19. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents. 20. Only one treatment attempt will be allowed per calendar year, regardless of compliance.
High Dose Opioids	Prior authorization is required for use of high-dose opioids ≥ 150 morphine milligram equivalents (MME) per day (See CDC Guideline for Prescribing Opioids for Chronic Pain at https://www.cdc.gov/drugoverdose/prescribing/guideline.html). Patients undergoing active cancer treatment or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met: 1. Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and 2. Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code. Requests for a diagnosis of fibromyalgia or migraine will not be considered; and 3. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and 4. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants; and 5. There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and 6. Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and 7. Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and 8. Chart notes from a recent office visit for pain management is included documenting the following: a. Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and b. Treatment goals; and 9. Patient has been informed of the risks of high-dose opioid therapy; and 10. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and 11. The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and 12. A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and 13. The requested dosing interval is no more frequent than the maximum FDA-approved dosing interval; and 14. Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and 15. Patient has been educated on opioid overdose prevention; and 16. Patient's household members have been educated on the signs of opioid overdose and how to administer naloxone; and 17. Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with initial and subsequent requests; and

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Use High Dose Opioids PA form	18. A documented dose reduction is attempted at least annually. If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 6 months with the following: 1. High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and 2. Patient has not experienced an overdose or other serious adverse event; and 3. Patient is not exhibiting warning signs of opioid use disorder; and 4. The benefits of opioids continue to outweigh the risks; and 5. A documented dose reduction has been attempted at least annually, and the prescriber has determined the dose cannot be reduced at this time; and 6. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that continued use of high-dose opioid therapy is appropriate for this patient; and 7. Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with subsequent requests. 8. Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and 9. Patient has been reeducated on opioid overdose prevention; and 10. Patient's household members have been reeducated on the signs of opioid overdose and how to administer naloxone.

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Updated 7/1/2019

Idiopathic Pulmonary Fibrosis *Use Idiopathic Pulmonary Fibrosis PA form*	Prior authorization is required for pirfenidone (Esbriet®) and nintedanib (Ofev®). Dosing outside of the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered. Payment will be considered for patients when the following criteria are met: 1. Patient is 40 years of age or older; and 2. Is prescribed by a pulmonologist; and 3. Patient has a diagnosis of idiopathic pulmonary fibrosis as confirmed by one of the following (attach documentation): a. Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or b. A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and 4. Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity; and 5. Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥50% predicted; and 6. Patient has a carbon monoxide diffusion capacity (%DLco) of ≥30% predicted; and 7. Patient does not have hepatic impairment as defined below: a. Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or b. Pifenidone - Patient does not have severe hepatic impairment (Child Pugh C); and 8. Patient does not have renal impairment as defined below: a. Nintedanib - Patient does not have severe renal impairment (CrCl <30ml/min) or end-stage renal disease or b. Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and 9. Patient is a nonsmoker or has been abstinent from smoking for at least six weeks. If the criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 6 month intervals when the following criteria are met: 1. Adherence to pirfenidone (Esbriet®) and nintedanib (Ofev®) is confirmed; and 2. Patient is tolerating treatment defined as improvement or maintenance of disease (<10% decline in percent predicted FVC or < 200 mL decrease in FVC); and 3. Documentation is provided that the patient has remained tobacco-free; and 4. ALT, AST, and bilirubin are assessed periodically during therapy.
Immunomodulators-Topical *Elidel®* *Protopic®* *Use Immunomodulators-Topical PA form*	Prior authorization is required for topical immunomodulators. Payment for non-preferred topical immunomodulator products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment for pimecrolimus (Elidel®) or tacrolimus (Protopic®) 0.03% will be considered for non-immunocompromised patients two years of age and older and tacrolimus (Protopic®) 0.1% for patients 16 years of age and older when there is an adequate trial and therapy failure with one preferred topical corticosteroid, except on the face or groin. If criteria for coverage are met, requests will be approved for one tube per 90 days to ensure appropriate short-term and intermittent utilization of the medication. Quantities will be limited to 30 grams for use on the face, neck, and groin, and 60 grams or 100 grams for all other areas. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Insulin, Pre-Filled Pens *Use Pre-filled Insulin Pen PA form*	Prior authorization (PA) is required for pre-filled insulin pens as designated on the Preferred Drug List (PDL). For pre-filled insulin pens requiring PA where the requested insulin is available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:: 1. The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin (not applicable for pediatric patients), and 2. There is no caregiver available to provide assistance, and 3. Patient does not reside in a long-term care facility, and 4. For requests for non-preferred pre-filled insulin pens, patient has documentation of a previous trial and therapy failure with a preferred pre-filled insulin pen within the same class (i.e. rapid, regular or basal). For pre-filled insulin pens requiring PA where the requested insulin is not available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria: 1. Preferred pre-filled insulin pens- Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal) or clinical rationale as to why the patient cannot use a preferred insulin agent, and 2. Non-preferred pre-filled insulin pens- Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal). 3. Requests for Toujeo will require clinical rationale as to why the patient cannot use Lantus and patient must be using a minimum of 100 units of Lantus per day.
Isotretinoin (Oral) *Use Oral Isotretinoin PA form*	Prior authorization is required for oral isotretinoin therapy. Payment will be approved for preferred oral isotretinoin products for acne under the following conditions: 1. There are documented trials and therapy failures of systemic antibiotic therapy and topical tretinoin therapy. Documented trials and therapy failures of systemic antibiotic therapy and topical tretinoin therapy are not required for approval for treatment of acne conglobata. 2. Patients and providers must be registered in, and meet all requirements of, the iPLEDGE (www.ipledgeprogram.com) risk management program. Payment for non-preferred oral isotretinoin products will be authorized only for cases in which there is documentation of trial(s) and therapy failure with a preferred agent(s). Initial authorization will be granted for up to 20 weeks. A minimum of two months without therapy is required to consider subsequent authorizations.

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Updated 7/1/2019

Ivabradine (Corlanor®) *Use Ivabradine (Corlanor®) PA form*	Prior authorization is required for ivabradine. Only FDA approved dosing will be considered. Payment will be considered under the following conditions: 1. Patient is 18 years of age or older; and 2. Patient has a diagnosis of stable, symptomatic heart failure (NYHA Class II, III, or IV); and 3. Patient has documentation of a left ventricular ejection fraction ≤35%; and 4. Patient is in sinus rhythm with a resting heart rate of ≥70 beats per minute; and 5. Patient has documentation of blood pressure ≥90/50 mmHg; and 6. Heart failure symptoms persist with maximally tolerated doses of at least one beta-blocker with proven mortality benefit in a heart failure clinical trial (e.g. carvedilol 50mg daily, metoprolol succinate 200mg daily, or bisoprolol 10mg daily), or patient has a documented intolerance or FDA labeled contraindication to beta-blockers; and 7. Patient has documentation of a trial and continued use with a preferred ACE inhibitor or preferred ARB at a maximally tolerated dose. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.
Ivacaftor (Kalydeco™) *Use Kalydeco™ PA form*	Prior authorization is required for Kalydeco™ (ivacaftor). Payment will be considered for patients when the following criteria are met: 1. Patient meets the FDA approved age; and 2. Has a diagnosis of cystic fibrosis; and 3. Patient has one of the CFTR gene mutations as indicated in the FDA approved label as detected by an FDA-cleared CF mutation test; and 4. Prescriber is a CF specialist or pulmonologist; and 5. Baseline liver function tests (AST/ALT) are provided; and If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met: 1. Adherence to ivacaftor therapy is confirmed; and 2. Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.

Iowa Medicaid Drug Prior Authorization Criteria

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Janus Kinase Inhibitors *Use Janus Kinase Inhibitor PA form*	Prior authorization is required for Janus kinase (JAK) inhibitors. Payment will be considered for a FDA approved or compendia indicated diagnosis when the following conditions are met: 1. Patient meets the FDA approved age; and 2. Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biologic DMARDs or potent immunosuppressants (azathiorpine or cyclosporine); and 3. Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and 4. Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to the manufacturer labeling; and 5. Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and 6. Patient is not at an increased risk of gastrointestinal perforation. 7. Patient does not have an active, serious infection, including localized infections; and 8. Medication will not be given concurrently with live vaccines; and 9. Follows FDA approved dosing based on indication; and 10. Patient has a diagnosis of: a. Moderate to severe rheumatoid arthritis; with i. A documented trial and inadequate response to two preferred oral disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, or leflunomide); and ii. A documented trial and inadequate response to two preferred biological DMARDs; OR b. Psoriatic arthritis; with i. A documented trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and ii. Documented trial and therapy failure with two preferred biological agents used for psoriatic arthritis. c. Moderately to severely active ulcerative colitis; with i. A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and ii. A documented trial and inadequate response with a preferred biological DMARD; and iii. If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

For all drugs requiring prior authorization, in the event of an emergency situation when a prior authorization request cannot be submitted and a response received within 24 hours such as after regular working hours or on weekends, a 72-hour supply of the drug may be dispensed and reimbursement will be made, unless otherwise noted in criteria. Certain drugs are allowed a 7 day supply while prior authorization is being requested. PDL IMPLEMENTATION DATE 01-15-05

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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Ketorolac *Use Ketorolac PA form*	Prior authorization is required for ketorolac tromethamine, a nonsteroidal anti-inflammatory drug indicated for short term (up to five days) management of moderately severe, acute pain. It is NOT indicated for minor or chronic conditions. This product carries a **Black Box Warning**. Initiate therapy with IV/IM and use oral ketorolac tromethamine only as a continuation therapy to ketorolac tromethamine IV/IM. The combined duration of use of IV/IM and oral is not to exceed five (5) days. Payment will be considered under the following conditions: 1. For oral therapy, documentation of recent IM/IV ketorolac tromethamine injection including administration date and time, and the total number of injections given. 2. Request falls within the manufacturer's dosing guidelines. Maximum oral dose is 40mg/day. Maximum IV/IM dose is 120mg/day. Maximum intranasal dose is 126mg/day. Maximum combined duration of therapy is 5 days per month. 3. Diagnosis indicating moderately severe, acute pain. Requests for IV/IM and intranasal ketorolac must document previous trials and therapy failures with at least two preferred non-steroidal anti-inflammatory drugs at therapeutic doses.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Lesinurad (Zurampic) *Use Lesinurad (Zurampic) PA form*	Prior authorization is required for lesinurad (Zurampic). Requests for doses above the FDA approved dose will not be considered. Requests will be considered for patients when the following criteria are met: 1. Patient is 18 years of age or older; and 2. Patient has a diagnosis of hyperuricemia associated with gout; and 3. Patient has not achieved target serum uric acid levels or patient remains symptomatic with a maximally tolerated dose of a xanthine oxidase inhibitor (allopurinol or febuxostat) for at least 3 months; and 4. Patient has documentation of a previous trial and therapy failure with probenecid in combination with a xanthine oxidase inhibitor; and 5. Patient has an estimated creatinine clearance (eCrCl) > 45 mL/min; and 6. Documentation is provided lesinurad will be used in combination with a xanthine oxidase inhibitor. a. If taking allopurinol, dose should be ≥300 mg per day (or ≥200 mg per day in patients with an eCrCl < 60 mL/min); and 7. Patient does not have a contraindication to therapy including any of the following: a. Severe renal impairment (eCrCl <30 mL/min), b. End stage renal disease, c. Kidney transplant recipient, d. On dialysis, e. Tumor lysis syndrome, or f. Lesch-Nyhan syndrome. If criteria for coverage are met, initial requests will be given for 6 months. Continuation of therapy will be considered when the following criteria are met: 1. Patient continues to take medication in combination with a xanthine oxidase inhibitor. a. If allopurinol, dose should be ≥300 mg per day (or ≥200 mg per day in patients with an eCrCl < 60 mL/min) 2. Patient has an eCrCl > 45 mL/min; and 3. Patient does not have a contraindication to therapy including any of the following: a. Severe renal impairment (eCrCl <30 mL/min), b. End stage renal disease, c. Kidney transplant recipient, d. On dialysis, e. Tumor lysis syndrome, or f. Lesch-Nyhan syndrome. 4. Documentation of a positive clinical response to lesinurad. The required trials may be overridden when documented evidence is provided that use of the agent(s) would be medically contraindicated.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Letermovir (Prevymis) *Use Letermovir (Prevymis) PA form*	Prior authorization is required for oral letermovir. Requests for intravenous letermovir should be directed to the member's medical benefit. Payment will be considered under the following conditions: 1. Medication is to be used for the prophylaxis of cytomegalovirus (CMV) infection and disease; and 2. Patient or donor is CMV-seropositive R+ (attach documentation); and 3. Patient has received an allogeneic hematopoietic stem cell transplant (HSCT) within the last 28 days (provide date patient received HSCT); and 4. Is prescribed by or in consultation with a hematologist, oncologist, infectious disease or transplant specialist; and 5. Patient is 18 years of age or older; and 6. Dose does not exceed: a. 240mg once daily when co-administered with cyclosporine; b. 480mg once daily; and 7. Patient must not be taking the following medications: a. Pimozide; or b. Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or c. Rifampin; or d. Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and 8. Patient does not have severe (Child-Pugh Class C) hepatic impairment (provide score); and 9. Therapy duration will not exceed 100 days post-transplantation.
Lidocaine Patch (Lidoderm®) *Use Lidocaine Patch (Lidoderm®) PA form*	Prior authorization is required for topical lidocaine patches. Payment will be considered only for cases in which there is a diagnosis of pain associated with post-herpetic neuralgia. A maximum of 30 patches may be dispensed with the initial prescription to determine efficacy.

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Updated 7/1/2019

Linezolid (Zyvox®) *Use linezolid (Zyvox®) PA form*	Prior authorization is required for linezolid (Zyvox®). Payment for linezolid (Zyvox®) will be authorized when there is documentation that: 1. Prescriber is an infectious disease (ID) physician or has consulted ID physician (Telephone consultation is acceptable). 2. Patient has an active infection and meets one of the following diagnostic criteria: a. Vancomycin-resistant Enterococcus (VRE) and no alternative regimens with documented efficacy are available and VRE is not in lower urinary tract**. b. Methicillin-resistant Staph aureus (MRSA) and patient is intolerant to vancomycin* c. Methicillin-resistant Staph epidermis (MRSE) and patient is intolerant to vancomycin* *Severe intolerance to vancomycin is defined as: 1. Severe rash, immune-complex mediated, determined to be directly related to vancomycin administration 2. Red-man's syndrome (histamine-mediated), refractory to traditional counter measures (e.g., prolonged IV infusion, premedicated with diphenhydramine) **VRE in lower urinary tract, considered to be pathogenic, may be treated with linezolid if severe renal insufficiency exists and/or patient is receiving hemodialysis or has known hypersensitivity to nitrofurantoin.

Iowa Medicaid Drug Prior Authorization Criteria

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Long-Acting Opioids *Use Long-Acting Opioids PA form*	Prior authorization (PA) is required for all non-preferred long-acting opioids. PA is also required for members when the total daily opioid use (combined across all opioids) exceeds the set morphine milligram equivalent (MME) threshold (include High Dose Opioids PA form with request). Payment will be considered under the following conditions: 1. Patient has a diagnosis of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment; and 2. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and 3. Patient has tried and failed at least two nonopioid pharmacologic therapies (e.g. acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and 4. There is documentation of previous trial and therapy failure with one preferred long-acting opioid at maximally tolerated dose; and 5. A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization; and 6. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website and determine if use of a long-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and. 7. Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids. 8. Requests for long-acting opioids will only be considered for FDA approved dosing intervals. As-needed (PRN) dosing will not be considered; and 9. For patients taking concurrent benzodiazepines, the prescriber must document the following: a. The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and b. Documentation as to why concurrent use is medically necessary is provided; and c. A plan to taper the benzodiazepine is provided, if appropriate. If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met: 1. Patient has experienced improvement in pain control and level of functioning; and 2. Prescriber has reviewed the patient's use of controlled substances on the Iowa PMP and has determined continued use of a long-acting opioid is appropriate for this member; and 3. For patients taking concurrent benzodiazepines, the prescriber must document the following: a. The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and b. Documentation as to why concurrent use is medically necessary is provided; and c. A plan to taper the benzodiazepine is provided, if appropriate. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

For all drugs requiring prior authorization, in the event of an emergency situation when a prior authorization request cannot be submitted and a response received within 24 hours such as after regular working hours or on weekends, a 72-hour supply of the drug may be dispensed and reimbursement will be made, unless otherwise noted in criteria. Certain drugs are allowed a 7 day supply while prior authorization is being requested. PDL IMPLEMENTATION DATE 01-15-05

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Lumacaftor/Ivacaftor (Orkambi™) *Use Lumacaftor/Ivacaftor (Orkambi) PA form*	Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met: 1. Patient meets the FDA approved age; and 2. Has a diagnosis of cystic fibrosis; and 3. Patient is homozygous for the *F508del* mutation in the *CFTR* gene as confirmed by a FDA-cleared CF mutation test; and 4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and 5. Prescriber is a CF specialist or pulmonologist. If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met: 1. Adherence to lumacaftor/ivacaftor therapy is confirmed; and 2. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.
Lupron Depot – Adult *Use Lupron Depot-Adult PA form*	Prior authorization is required for Lupron Depot (leuprolide acetate). Payment will be considered for patients under the following conditions: 1. Patient is 18 years of age or older; and 2. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and 3. Patient has a diagnosis of endometriosis for whom therapy with NSAIDs and at least one preferred 3 month course of a continuous hormonal contraceptive has failed; or 4. Patient has a diagnosis of uterine leiomyomata with anemia (hematocrit < 30 g/dL or hemoglobin < 10 g/dL) that did not respond to treatment with at least a one month trial of iron and is to be used preoperatively; or 5. Patient has a diagnosis of advanced prostate cancer. Therapy will be limited as follows: 1. Endometriosis – initial 6 month approval. If symptoms of endometriosis recur after the first course of therapy, a second course of therapy with concomitant norethindrone acetate 5 mg daily will be considered. Retreatment is not recommended for longer than one additional 6 month course. 2. Uterine leiomyomata – 3 month approval. 3. Advanced prostate cancer – initial 6 month approval. Renewal requests must document suppression of testosterone levels towards a castrate level of < 50 ng/dL (attach lab).

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Lupron Depot – Pediatric *Use Lupron Depot-Pediatric PA form*	Prior authorization is required for Lupron Depot-Ped. Payment will be considered for patients when the following is met: 1. Patient has a diagnosis of central precocious puberty (CPP); and 2. Patient has documentation of onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males; and 3. Patient is currently < 11 years of age for females or < 12 years of age for males; and 4. Confirmation of diagnosis by a pubertal response to a gonadotropin-releasing hormone (GnRH) stimulation test is provided (attach results); and 5. Documentation of advanced bone age (defined as greater than or equal to two standard deviations above the gender/age related mean); and 6. Baseline evaluations including the following have been conducted and/or evaluated: a. Height and weight measurements; and b. Sex steroid (testosterone or estradiol) levels have been obtained; and c. Appropriate diagnostic imaging of the brain has been conducted to rule out an intracranial tumor; and d. Pelvic/testicular/adrenal ultrasound has been conducted to rule out steroid secreting tumors; and e. Human chorionic gonadotropin levels have been obtained to rule out a chorionic gonadotropin secreting tumor; and f. Adrenal steroid levels have been obtained to rule out congenital adrenal hyperplasia; and 7. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility. When criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted at 6 month intervals until the patient is ≥ 11 years of age for females and ≥ 12 years of age for males. If therapy beyond the aforementioned ages is required, documentation of medical necessity will be required.

Iowa Medicaid Drug Prior Authorization Criteria

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Methotrexate Injection *Otrexup™* *Rasuvo®* *Use Methotrexate Injection PA form*	Prior authorization is required for non-preferred methotrexate injection. Payment will be considered under the following conditions: 1. Diagnosis of severe, active rheumatoid arthritis (RA) or polyarticular juvenile idiopathic arthritis (pJIA) and ALL of the following: a. Prescribed by a rheumatologist; and b. Patient has a documented trial and intolerance with oral methotrexate; and c. Patient has a documented trial and therapy failure or intolerance with at least one other non-biologic DMARD (hydroxychloroquine, leflunomide, or sulfasalazine); and d. Patient's visual or motor skills are impaired to such that they cannot accurately draw up their own preferred generic methotrexate injection and there is no caregiver available to provide assistance; and e. Patient does not reside in a long-term care facility. 2. Diagnosis of severe, recalcitrant, disabling psoriasis and ALL of the following: a. Patient is 18 years of age or older; and b. Prescribed by a dermatologist; and c. Patient has documentation of an inadequate response to all other standard therapies (oral methotrexate, topical corticosteroids, vitamin D analogues, cyclosporine, systemic retinoids, tazarotene, and phototherapy). d. Patient's visual or motor skills are impaired to such that they cannot accurately draw up their own preferred generic methotrexate injection and there is no caregiver available to provide assistance; and e. Patient does not reside in a long-term care facility. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
Miconazole-Zinc Oxide-White Petrolatum (Vusion) Ointment *Use Miconazole-Zinc Oxide-White Petrolatum (Vusion) Ointment PA form*	Prior Authorization is required for miconazole-zinc oxide-white petrolatum (Vusion) Ointment. Payment will only be considered for cases in which there is documentation of previous trials and therapy failures with 1) over-the-counter miconazole 2% cream (payable with a prescription) AND 2) nystatin cream or ointment, unless evidence is provided that use of these agents would be medically contraindicated.
Mifepristone (Korlym®) *Use Mifepristone (Korlym) PA form*	Prior authorization is required for mifepristone (Korlym®). Payment will be considered for patients when the following is met: 1. The patient is 18 years of age or older: and 2. Has a diagnosis of endogenous Cushing's Syndrome with hyperglycemia secondary to hypercortisolism in patients with Type 2 Diabetes or glucose intolerance: and 3. Patient must have failed surgery or is not a candidate for surgery: and 4. Prescriber is an endocrinologist: and 5. Female patients of reproductive age must have a negative pregnancy test confirmed within the last 7 days and must use a non-hormonal method of contraception during treatment and for one month after stopping treatment.

For all drugs requiring prior authorization, in the event of an emergency situation when a prior authorization request cannot be submitted and a response received within 24 hours such as after regular working hours or on weekends, a 72-hour supply of the drug may be dispensed and reimbursement will be made, unless otherwise noted in criteria. Certain drugs are allowed a 7 day supply while prior authorization is being requested. PDL IMPLEMENTATION DATE 01-15-05

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Milnacipran (Savella) *Use Chronic Pain Syndromes PA form*	*See Chronic Pain Syndromes Prior Authorization Criteria.*
Modified Formulations *Use Modified Formulations PA form*	Payment for a non-preferred isomer, prodrug, or metabolite will be considered when the following criteria are met: 1. Previous trial with a preferred parent drug of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance and 2. Previous trial and therapy failure at a therapeutic dose with a preferred drug of a different chemical entity indicated to treat the submitted diagnosis if available. The required trials may be overridden when documented evidence is provided that use of these preferred agent(s) would be medically contraindicated. Prior authorization is required for the following modified dosage forms: Abilify Discmelt, Aricept ODT, Binosto, FazaClo, Horizant, Invega, Metoclopramide ODT, Remeron SolTab, Risperdal M-Tab, Sitavig, Spritam, Trilipix, Xopenex, Zyprexa Zydis.

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Updated 7/1/2019

Multiple Sclerosis Agents-Oral *Use Multiple Sclerosis Agents-Oral PA form*	For patients initiating therapy with a preferred oral medication, a manual prior authorization is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided: 1. A diagnosis of relapsing forms of multiple sclerosis; and 2. Patient meets the FDA approved age; and 3. A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis. 4. Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. For patients initiating therapy with fingolimod (Gilenya): 1. Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class lll/lV heart failure. 2. Patient does not have a history or presence of Mobitz Type ll 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker. 3. Patient does not have a baseline QTc interval ≥ 500ms. 4. Patient is not being treated with Class la or Class lll anti-arrhythmic drugs. For patients initiating therapy with teriflunomide (Aubagio): 1. Patient does not have severe hepatic impairment. 2. A negative pregnancy test for females of childbearing age. 3. Use of a reliable form of contraception for females of childbearing age. 4. Patient is not taking leflunomide. For patients initiating therapy with dimethyl fumarate (Tecfidera): 1. Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy. 2. Upon renewal, documentation of an updated CBC.
Muscle Relaxants *Use Muscle Relaxant PA form*	Prior authorization is required for non-preferred muscle relaxants. Payment for non-preferred muscle relaxants will be authorized only for cases in which there is documentation of previous trials and therapy failures with at least three preferred muscle relaxants. Requests for carisoprodol will be approved for a maximum of 120 tablets per 180 days at a maximum dose of 4 tablets per day when the criteria for coverage are met. * If a non-preferred long-acting medication is requested, one trial must include the preferred immediate release product of the same chemical entity at a therapeutic dose, unless evidence is provided that use of these products would be medically contraindicated.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Narcan (Naloxone) Nasal Spray *Use Narcan (Naloxone) Nasal Spray PA form*	Prior authorization is required for a patient requiring more than 2 doses of Narcan (naloxone) nasal spray per 365 days. Requests for quantities greater than 2 doses per 365 days will be considered under the following conditions: 1. Documentation is provided indicating why patient needs additional doses of Narcan (naloxone) nasal spray (accidental overdose, intentional overdose, other reason); and 2. Narcan (naloxone) nasal spray is to be used solely for the patient it is prescribed for; and 3. The patient is receiving an opioid as verified in pharmacy claims; and 4. Patient has been reeducated on opioid overdose prevention; and 5. Documentation is provided on the steps taken to decrease the chance of opioid overdose again; and 6. A treatment plan is included documenting a plan to lower the opioid dose.
Narcotic Agonist-Antagonist Nasal Sprays *Use Narcotic Agonist/Antagonist Nasal Spray PA form*	Prior authorization is required for narcotic agonist-antagonist nasal sprays. For consideration, the diagnosis must be supplied. If the use is for the treatment of migraine headaches, documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications must be provided. There must also be documented treatment failure or contraindication to triptans for the acute treatment of migraines. For other pain conditions, there must be documentation of treatment failure or contraindication to oral administration. Payment for non-preferred narcotic agonist-antagonist nasal sprays will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. Quantities are limited to 2 bottles or 5 milliliters per 30 days. Payment for narcotic agonist-antagonist nasal sprays beyond this limit will be considered on an individual basis after review of submitted documentation.
Nebivolol (Bystolic®) *Use Nebivolol (Bystolic®) PA form*	Prior authorization is required for Bystolic®. Payment will be considered in cases where there are documented trials and therapy failures with two preferred cardio-selective beta-blockers of a different chemical entity at a therapeutic dose. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Iowa Medicaid Drug Prior Authorization Criteria

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Updated 7/1/2019

New to Market Drugs *Use New to Market Drugs PA form*	Prior authorization is required for newly marketed drugs. Payment will be considered for patients when the following criteria are met: 1. Patient has an FDA approved or compendia indication for the requested drug; and 2. If the requested drug falls in a therapeutic category/class with existing prior authorization criteria, the requested drug must meet the criteria for the same indication; or 3. If no clinical criteria are established for the requested drug, patient has tried and failed at least two preferred drugs, when available, from the Iowa Medicaid Preferred Drug List (PDL) for the submitted indication; and 4. Request must adhere to all FDA approved labeling. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated. Once newly marketed drugs are reviewed by the Pharmaceutical & Therapeutics Committee, they will be placed on the PDL which will dictate ongoing PA criteria, if applicable.
Nocturnal Polyuria Treatments *Use Nocturnal Polyuria Treatments PA form*	Prior authorization is required for nocturnal polyuria treatments. Payment will be considered for patients when the following criteria are met: 1. Patient meets the FDA approved age; and 2. Patient has a diagnosis of nocturnal polyuria as confirmed by a 24-hour collection which notes the presence of greater than 33% of 24-hour urine productions occurring at night; and 3. Patient wakens at least 2 times at night to void; and 4. Patient has attempted fluid restriction in the evenings without improvement in nocturnal polyuria; and 5. Patient is not taking a diuretic in the evening; and 6. Patient does not have any of the following contraindications a) Current or previous history of hyponatremia; and b) Primary nocturnal enuresis; and c) Polydipsia; and d) Concomitant use with loop diuretics, systemic or inhaled glucocorticoids; and e) Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion; and f) Estimated glomerular filtration rate < 50 mL/min.1.73m^2; and g) Illnesses that can cause fluid or electrolyte imbalance; and h) New York Heart Association (NYHA) Class ll-lV congestive heart failure; and i) Uncontrolled hypertension. Initial requests will be considered for 3 months. Requests for continuation of therapy will require the following: 1. Patient continues to meet above criteria; and 2. Patient has experienced a decrease in nocturnal voiding; and 3. There is no evidence of toxicity (e.g., hyponatremia, fluid retention, or electrolyte imbalances).

For all drugs requiring prior authorization, in the event of an emergency situation when a prior authorization request cannot be submitted and a response received within 24 hours such as after regular working hours or on weekends, a 72-hour supply of the drug may be dispensed and reimbursement will be made, unless otherwise noted in criteria. Certain drugs are allowed a 7 day supply while prior authorization is being requested. PDL IMPLEMENTATION DATE 01-15-05

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products *Use Non-Parenteral Vasopressin Deriv. of Posterior Pituitary Hormone Products PA form*	Prior authorization is required for non-parenteral vasopressin derivatives of posterior pituitary hormone products. Payment for preferred non-parenteral vasopressin derivatives of posterior pituitary hormone products will be authorized for the following diagnoses: 1. Diabetes Insipidus. 2. Hemophilia A. 3. Von Willebrand's disease. Requests for desmopressin nasal spray for the treatment of nocturnal enuresis will not be considered. Payment for non-preferred non-parenteral vasopressin derivatives will be authorized only for cases in which there is documentation of trial and therapy failure with the preferred agent. Please refer to the Selected Brand-Name Drugs prior authorization form is requesting a non-preferred brand-name product.
Non-Preferred Drug *Use Non-Preferred Drug PA form*	Prior authorization is required for non-preferred drugs as specified on the Iowa Medicaid Preferred Drug List. Payment for a non-preferred medication will be authorized only for cases in which there is documentation of previous trial and therapy failure with the preferred agent, unless evidence is provided that use of these agents would be medically contraindicated.
Nonsteroidal Anti-inflammatory Drugs *Use Non-Steroidal Anti-inflammatory Drug PA form*	Prior authorization is required for all non-preferred nonsteroidal anti-inflammatory drugs (nsaids) and COX-2 inhibitors. Prior authorization is not required for preferred nonsteroidal anti-inflammatory drugs or COX-2 inhbitors. 1. Requests for a non-preferred nsaid must document previous trials and therapy failures with at least three preferred nsaids. 2. Requests for a non-preferred COX-2 inhibitor must document previous trials and therapy failures with three preferred nsaids, two of which must be a preferred COX-2 preferentially selective nsaid. 3. Requests for a non-preferred extended release nsaid must document previous trials and therapy failures with three preferred nsaids, one of which must be the preferred immediate release nsaid of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Novel Oral Anticoagulants *Use Novel Oral Anticoagulants PA form*	Prior authorization is not required for preferred novel oral anticoagulants (NOACs). Prior authorization is required for non-preferred NOACs. Requests for doses outside of the manufacturer recommended dose will not be considered. Payment will be considered for FDA approved or compendia indications under the following conditions: 1. Patient does not have a mechanical heart valve; and 2. Patient does not have active bleeding; and 3. For a diagnosis of atrial fibrillation or stroke prevention, patient has the presence of at least one additional risk factor for stroke, with a CHA_2DS_2-VASc score ≥ 1; and 4. A recent creatinine clearance (CrCl) is provided; and 5. A recent Child-Pugh score is provided; and 6. Patient's current body weight is provided; and 7. Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred NOACs. 8. For requests for edoxaban, documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin). The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Iowa Medicaid Drug Prior Authorization Criteria

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Oral Constipation Agents *Use Oral Constipation Agents PA form*	Prior authorization is required for oral constipation agents subject to clinical criteria. Payment for non-preferred oral constipation agents will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred oral constipation agent. Payment will be considered under the following conditions: 1. Patient meets the FDA approved age; and 2. Patient must have documentation of adequate trials and therapy failures with both of the following: a. Stimulant laxative (senna) plus saline laxative (milk of magnesia); and b. Stimulant laxative (senna) plus osmotic laxative (polyethylene glycol or lactulose); and 3. Patient does not have a known or suspected mechanical gastrointestinal obstruction; and 4. Patient has one of the following diagnoses: a. A diagnosis of chronic idiopathic constipation (Amitiza®, Linzess™, Trulance®) i. Patient has less than 3 spontaneous bowel movements (SBMs) per week; and ii. Patient has two or more of the following symptoms within the last 3 months: 1. Straining during at least 25% of bowel movements; 2. Lumpy or hard stools for at least 25% of bowel movements; and 3. Sensation of incomplete evacuation for at least 25% of bowel movements; and iii. Documentation the patient is not currently taking constipation causing therapies b. A diagnosis of irritable bowel syndrome with constipation (Amitiza®,Linzess™, or Trulance®) i. Patient is female (Amitiza® only); and ii. Patient has recurrent abdominal pain on average at least 1 day per week in the last 3 months associated with two (2) or more of the following: 1. Related to defecation; 2. Associated with a change in stool frequency; and/or 3. Associated with a change in stool form c. A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza®, Movantik™, Relistor®, or Symproic®) i. Patient has been receiving stable opioid therapy for at least 30 days as seen in the patient's pharmacy claims; and ii. Patient has less than 3 spontaneous bowel movements (SBMs) per week, with at least 25% associated with one or more of the following: 1. hard to very hard stool consistency; 2. Moderate to very severe straining; and/or 3. Having a sensation of incomplete evacuation If the criteria for coverage are met, initial authorization will be given for 12 weeks to assess the response to treatment. Requests for continuation of therapy may be provided if prescriber documents adequate response to treatment.

For all drugs requiring prior authorization, in the event of an emergency situation when a prior authorization request cannot be submitted and a response received within 24 hours such as after regular working hours or on weekends, a 72-hour supply of the drug may be dispensed and reimbursement will be made, unless otherwise noted in criteria. Certain drugs are allowed a 7 day supply while prior authorization is being requested. PDL IMPLEMENTATION DATE 01-15-05

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered. All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Oral Immunotherapy *Grastek®* *Ragwitek®* Oralair® *Use Oral Immunotherapy PA form*	Prior authorization is required for sublingual allergen immunotherapy. Payment will be considered under the following conditions: 1. Medication is prescribed in consultation with an allergist; and 2. Patient is diagnosed with pollen-induced allergic rhinitis with or without conjunctivitis; and 3. Patient has documented trials and therapy failures with allergen avoidance and pharmacotherapy (intranasal corticosteroids and antihistamines); and 4. Patient has a documented intolerance to immunotherapy injections; and 5. The first dose has been administered under the supervision of a health care provider to observe for allergic reactions (date of administration and response required prior to consideration). 6. If patient receives other immunotherapy by subcutaneous allergen immunotherapy (SCIT), treatment of allergic rhinitis with sublingual allergen immunotherapy (SLIT) will not be approved. <u>Short Ragweed Pollen (Ragwitek®) In addition to the above criteria being met:</u> 1. Patient is 18 through 65 years of age; and 2. Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to short ragweed pollen. 3. If criteria for coverage are met, authorization will be considered at least 12 weeks before the expected onset of ragweed pollen season and continued throughout the season. <u>Grass Pollen (Grastek® and Oralair®) In addition to the above criteria being met:</u> Oralair® 1. Patient is 10 through 65 years of age; and 2. Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to sweet vernal, orchard/cocksfoot, perennial rye, timothy, and Kentucky blue/June grass. 3. If criteria for coverage are met, authorization will be considered at least 4 months prior to the expected onset of each grass pollen season and continued throughout the grass pollen season. Grastek® 1. Patient is 5 through 65 years of age; and 2. Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to timothy grass (or cross reactive grasses such as sweet vernal, orchard/cocksfoot, perennial rye, Kentucky blue/June, meadow fescue, and redtop). 3. If criteria for coverage are met, authorization will be considered at least 12 weeks before the expected onset of each grass pollen season.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Palivizumab (Synagis®) *Use Palivizumab PA form*	Respiratory Syncytial Virus (RSV) Season is defined by the centers for disease control and prevention of the United States department of health and human services and described in the RSV surveillance reports published annually in the Morbidity and Mortality Weekly Report (MMWR) and available at http://www.cdc.gov/surveillance/nrevss/rsv/reports.html. 1. Medicaid will use virology data provided by the Iowa department of public health (IDPH) to prospectively estimate the start of the RSV season and follow the virology data to the end of the season. 2. Medicaid will provide coverage of prescription drugs that protect against RSV consistent with the current American Academy of Pediatrics (AAP) Guidelines for Infants and Children at Risk for Severe Illness due to RSV Infection. 3. The start date will begin two weeks prior to the expected season start date for the state of Iowa. The start date will be adjusted to an earlier date by Medicaid if indicated by the virological data. The expected season start date shall be derived from the median start date of the past 5 seasons using Iowa virological data. Prior authorization is required for therapy with palivizumab. Prior authorizations will be approved for administration during the RSV season for a maximum of five doses per patient. No allowances will be made for a sixth dose. Patients, who experience a breakthrough RSV hospitalization, should have their monthly prophylaxis discontinued, as there is an extremely low likelihood of a second RSV hospitalization in the same season. Payment for palivizumab will be considered for patients who meet one of the following criteria: <u>Chronic Lung Disease (CLD) of Prematurity</u> 1. Patient is less than 12 months of age at start of therapy and has CLD of prematurity (defined as gestational age less than 32 weeks and required greater than 21% oxygen for at least the first 28 days after birth). 2. Requests for patients during their second year of life (12 months to < 24 months) will be considered for patients meeting the CLD of prematurity definition above and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season. <u>Prematurity (without CLD of Prematurity or Congenital Heart Disease)</u> 1. Patient is less than 12 months of age at start of therapy with a gestational age of less than 29 weeks. <u>Neuromuscular Disorders or Anatomic Pulmonary Abnormalities</u> 1. Patient is 12 months of age or younger at the start of therapy and has either severe neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway due to an ineffective cough. <u>Hemodynamically Significant Congenital Heart Disease (CHD)</u> 1. Patient is less than 12 months of age at start of therapy and has hemodynamically significant CHD further defined by any of the following: Acyanotic heart disease receiving medication to control congestive heart failure and will require cardiac surgical procedures, moderate to severe pulmonary hypertension, or cyanotic heart defects with documentation of consultation with a pediatric cardiologist that recommends palivizumab prophylaxis. <u>Immunocompromised Children</u> 1. Patient is less than 24 months of age at start of therapy and is profoundly immunocompromised during the RSV season (e.g., severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, receiving chemotherapy).

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

PCSK9 Inhibitors *Praluent*® *Repatha*™	Prior authorization is required for PCSK9 Inhibitors. Payment for non-preferred PCSK9 Inhibitors will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent, when available for the submitted diagnosis. Payment will be considered under the following conditions: 1. Patient is 18 years of age or older (or, for Homozygous Familial Hypercholesterolemia patient is 13 years of age or older); AND 2. Current use of a statin and documentation of adherence to prescribed lipid lowering medications for the previous 90 days is provided (further defined below, by diagnosis); AND 3. Is to be prescribed as an adjunct to a low fat diet; AND 4. A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; AND 5. Documentation patient has been counseled on importance of abstinence from tobacco and, if a current smoker, be encouraged to enroll in a smoking cessation program; AND 6. Is prescribed by a lipidologist, cardiologist, or endocrinologist. 7. The 72-hour emergency supply rule does not apply to PCSK9 Inhibitors. 8. Prescriber and dispensing pharmacy will educate the patient on proper storage and administration. Improperly stored medications will not be replaced. 9. Lost or stolen medication replacement requests will not be authorized. 10. Goal is defined as a 50% reduction in untreated baseline LDL-C. 11. Is prescribed for one of the following diagnoses: <u>Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)</u> 1. Total cholesterol > 290mg/dL or LDL-C > 190mg/dL; AND a. Presence of tendon xanthomas; OR b. In first or second degree relative, one of the following: i. Documented tendon xanthomas; or ii. MI at age ≤60 years; or iii. Total cholesterol > 290mg/dL; OR c. Confirmation of diagnosis by gene or receptor testing (attach results); AND 2. Unable to reach goal LDL-C with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), PLUS ezetimibe (Zetia) 10mg daily, PLUS cholestyramine daily. <u>Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)</u> 1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; AND 2. Unable to reach goal LDL-C with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), PLUS ezetimibe (Zetia) 10mg daily, PLUS cholestyramine daily. <u>Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) – Repatha (evolocumab) only</u> 1. Total cholesterol and LDL-C > 600mg/dL and triglycerides within reference range; OR

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Use PCSK9 Inhibitors PA form	2. Confirmation of diagnosis by gene or receptor testing (attach results); AND 3. Unable to reach goal LDL-C with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), PLUS ezetimibe (Zetia) 10mg daily, PLUS cholestyramine daily. The required trials (excluding the statin trial) may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Initial and Renewal Authorizations HeFH or ASCVD Initial 1. Praluent 75mg or Repatha 140mg every 2 weeks for 8 weeks (4 doses). Renewal 1. Lipid profile required at week 8, week 24, and every 6 months thereafter; and 2. Patient continues therapy with a maximally tolerated statin dose and remains at goal; and 3. Patient has continued compliance with a low fat diet; and Praluent 1. If LDL-C at goal, continue therapy at 75mg every 2 weeks for 24 weeks. 2. If LDL-C not at goal, dose increase to 150mg every 2 weeks for 8 weeks (4 doses) and repeat LDL-C in 8 weeks. a. If repeat LDL-C not at goal, discontinue Praluent. b. If repeat LDL-C at goal, continue therapy at 150mg every 2 weeks for 24 weeks; or Repatha 1. If LDL-C at goal, continue therapy at 140mg every 2 weeks for 24 weeks. 2. If LDL-C not at goal, discontinue Repatha. HoFH (Repatha only) Initial 1. Repatha 420mg (3x140mg autoinjectors) every month for 3 months. Renewal 1. Lipid profile required after 3 months (third dose) and every 6 months thereafter; and 2. Continued therapy with a maximally tolerated statin dose. a. If LDL-C at goal, continue therapy at 420mg every month for six months. b. If LDL-C not at goal, discontinue Repatha*;* and 3. Patient has continued compliance with a low fat diet. Quantity Limits Praluent/Repatha for HeFH or ASCVD 1. A quantity limit of one syringe/pen/autoinjector per fill will apply (requires refill every 14 days). Repatha for HoFH only 1. A quantity limit of one three-pack per month

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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Potassium Binders *Use Potassium Binders PA form*	Prior authorization (PA) is required for non-preferred potassium binders. Payment will be considered under the following conditions: 1. Patient is 18 years of age or older; and 2. Patient has a diagnosis of chronic hyperkalemia; and 3. Patient has documentation of a recent trial and therapy failure with sodium polystyrene sulfonate. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
Pregabalin (Lyrica®) *Use Chronic Pain Syndromes PA form*	*See Chronic Pain Syndromes Prior Authorization Criteria.*
Proton Pump Inhibitors *Use Proton Pump Inhibitor PA form*	Prior authorization is not required for preferred proton pump inhibitors (PPI) for doses within the established quantity limits of one unit per day. Requests for PPIs exceeding one unit per day will be considered for the following diagnoses with additional documentation regarding the medical necessity: 1. Barrett's esophagus (Please fax a copy of the scope results with the initial request) 2. Erosive esophagitis (Please fax a copy of the scope results with the initial request) 3. Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, and multiple endocrine adenomas). 4. Recurrent peptic ulcer disease 5. Gastroesophageal reflux disease will be considered after documentation of a therapeutic trial and therapy failure with concomitant use of once daily PPI dosing and a bedtime dose of a histamine H2-receptor antagonist. Upon failure of the combination therapy, subsequent requests for PPIs exceeding one unit per day will be considered on a short term basis (up to 3 months). After the three month period, a retrial of the recommended once daily dosing will be required. A trial of the recommended once daily dosing will be required on an annual basis for those patients continuing to need doses beyond one unit per day. 6. Helicobacter pylori will be considered for up to 14 days of treatment with documentation of active infection. Payment for a non-preferred proton pump inhibitor will be authorized only for cases in which there is documentation of previous trials and therapy failures with three preferred products.
Pulmonary Arterial Hypertension Agents *Use Pulmonary Arterial Hypertension Agents PA form*	Prior Authorization is required for agents used to treat pulmonary hypertension. Payment will be approved under the following conditions: 1. Diagnosis of pulmonary arterial hypertension

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Quantity Limit Override *Use Quantity Limit Override PA form*	Designated drugs are limited to specific quantity limitations. These drugs are identified on the Iowa Medicaid Quantity Limit Chart posted on the website www.iowamedicaidpdl.com under the Billing/Quantity Limits tab. Providers should submit a Prior Authorization request for override consideration.
Repository Corticotropin Injection (H.P. Acthar Gel) *Use Repository Corticotropin Injection (H.P. Acthar Gel) PA form*	Prior authorization is required for repository corticotropin injection. Payment will be considered under the following conditions: 1. Patient is under two years of age and 2. Patient has a diagnosis of infantile spasms. Treatment of compendia indicated steroid-responsive conditions will only be considered upon documented contraindications or intolerance to corticosteroids not expected to occur with the use of repository corticotropin injection. If criteria for coverage are met, authorization will be provided for up to 30 days of treatment for all indications.
Rifaximin (Xifaxan®) *Use Rifaximin (Xifaxan®) PA form*	Prior authorization is required for rifaximin. Only FDA approved dosing will be considered. Payment will be considered under the following conditions: 1. A diagnosis of travelers' diarrhea: a. Patient is 12 years of age or older; and b. Patient has a diagnosis of travelers' diarrhea not complicated by fever or blood in the stool or diarrhea due to pathogens other than *Escherichia coli*; and c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred generic fluoroquinolone or azithromycin. d. A maximum 3 day course of therapy (9 tablets) of the 200mg tablets per 30 days will be allowed. 2. A diagnosis of hepatic encephalopathy: a. Patient is 18 years of age or older; and b. Patient has a diagnosis of hepatic encephalopathy; and c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with lactulose. 3. A diagnosis of irritable bowel syndrome with diarrhea: a. Patient is 18 years of age or older; and b. Patient has a diagnosis of irritable bowel syndrome with diarrhea; and c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred antispasmotic agent (dicyclomine, hyoscyamine); and d. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with amitriptyline and loperamide. e. If criteria for coverage are met, a single 14-day course will be approved. f. Subsequent requests will require documentation of recurrence of IBS-D symptoms. A minimum 10 week treatment-free period between courses is required. g. A maximum of 3 treatment courses of rifaximin will be allowed per lifetime. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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Roflumilast (Daliresp™) *Use Roflumilast (Daliresp™) PA form*	Prior authorization is required for roflumilast (Daliresp™). Payment will be considered for patients 18 years of age or older when the following is met: 1. A diagnosis of severe COPD with chronic bronchitis as documented by spirometry results, and 2. A smoking history of ≥ 20 pack-years, and 3. Currently on a long-acting bronchodilator in combination with an inhaled corticosteroid with documentation of inadequate control of symptoms, and 4. A history of at least one exacerbation in the past year requiring treatment with oral glucocorticosteroids. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
Sapropterin (Kuvan) *Use Sapropterin (Kuvan) PA form*	Prior authorization is required for sapropterin (Kuvan). Requests for doses above the FDA approved dose will not be considered. Initial requests will be considered for patients when the following criteria are met: 1. Patient has a diagnosis of phenylketonuria (PKU); and 2. Patient is on a phenylalanine (Phe) restricted diet prior to therapy and will continue throughout therapy; and 3. Patient has a baseline blood Phe level ≥360 micromol/L while following a Phe restricted diet, obtained within 2 weeks of initiation of sapropterin therapy (attach lab results); and 4. Patient's current weight is provided; and 5. Request is for an FDA approved starting dose (10mg/kg/day for patients 1 month to 6 years and 10-20mg/kg/day for patients 7 years and older); and 6. Blood Phe levels will be measured after 1 week of therapy and at least one other time during the first month of therapy. Initial requests will be considered for 1 month to assess response to therapy. Continuation of therapy will be considered when the following criteria are met: 1. Patient's current weight is provided; and 2. Patient continues on a Phe restricted diet; and 3. For patients initiated at a dose of 10mg/kg/day and the blood Phe level did not decrease from baseline, dose may be increased to 20mg/kg/day. Approval will be given for 1 month to assess response to therapy. 4. For patients initiated at a dose of 20mg/kg/per day or those increased to this dose after 1 month of therapy at 10mg/kg/day, an updated blood Phe level must be provided documenting response to therapy, defined as at least a 30% reduction in blood Phe level. If blood Phe level does not decrease after 1 month at 20mg/kg/day, the patient is considered a non-responder and no further requests will be approved. 5. Maintenance dose requests will be considered for patients that have responded to therapy, based on the above criteria, at 6 month intervals. Documentation of compliance to diet and updated blood Phe levels documenting continued response to therapy are required for further consideration.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Sedative/Hypnotics-Non-Benzodiazepine *Use Sedative/Hypnotics-Non-Benzodiazepine PA form*	Preferred agents are available without prior authorization (PA) when dosed within the established quantity limits. Requests for doses above the manufacturer recommended dose will not be considered. Prior authorization is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be authorized only for cases in which there is documentation of previous trials and therapy failures with, at a minimum, three (3) preferred agents. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be considered when the following criteria are met: 1. A diagnosis of insomnia; and 2. Medications with a side effect of insomnia (i.e. stimulants) are decreased in dose, changed to a short acting product, and/or discontinued; and 3. Enforcement of good sleep hygiene is documented; and 4. All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses. 5. In addition to the above criteria, requests for suvorexant (Belsomra) will require documentation of a trial and therapy failure with at least one non-preferred agent, other than suvorexant, prior to consideration of coverage. 6. Non-preferred alternative delivery systems will only be considered for cases in which the use of the alternative delivery system is medically necessary and there is a previous trial and therapy failure with a preferred alternative delivery system if available. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
Select Oncology Agents (Drugs included on the right) *Use Select Oncology Agents PA form*	Prior authorization is required for select oncology agents. Patient must have a diagnosis that is indicated in the FDA approved package insert or the use is for an indication supported by the compendia (including National Comprehensive Cancer Network (NCCN) compendium level of evidence 1, 2A, or 2B). The following must be submitted with the prior authorization request: copies of medical records (i.e. diagnostic evaluations and recent chart notes), location of treatment (provider office, facility, home health, etc.) if medication requested is not an oral agent, the original prescription, and the most recent copies of related laboratory results. If criteria for coverage are met, initial authorization will be given for three (3) months. Additional authorizations will be considered for up to six (6) month intervals when criteria for coverage are met. Updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued unless otherwise justified.
Selected Brand Name Drugs *Use Selected Brand Name PA forms*	Prior authorization is required for selected brand-name drugs, as determined by the Department, for which there is available an "A" rated bioequivalent generic product as determined by the Federal Food and Drug Administration, unless the brand drug has been designated by the Department as preferred (payable) under the Iowa Medicaid Preferred Drug List (PDL). For prior authorization to be considered, the prescriber must submit a completed Selected Brand Name PA form and Iowa Medicaid MedWatch form with: 1. Documentation of trials and therapy failures with two different generic manufacturers of the same chemical entity. If an allergy to an inactive component is suspected, the second trial must be with a generic product that does not contain the allergen, if available. 2. Documentation of the failure must include the specific adverse reaction as defined by the FDA (See Section B of the MedWatch form). Intolerances, such as nausea or vomiting, to the generic drug will not be considered as a basis for approval. Trials may be overridden when evidence is provided that use of the generic product would be medically contraindicated.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Serotonin 5-HT1-receptor Agonists *Use Serotonin 5-HT1-receptor Agonists PA form*	Prior authorization is required for preferred serotonin 5-HT1-receptor agonists for quantities exceeding 12 unit doses of tablets, syringes or sprays per 30 days. Payment for serotonin 5-HT1-receptor agonists beyond this limit will be considered on an individual basis after review of submitted documentation. Prior authorization will be required for all non-preferred serotonin 5-HT1-receptor agonists as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for non-preferred serotonin 5-HT1-receptor agonists will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred agents. Requests for non-preferred combination products may only be considered after documented separate trials and therapy failures with the individual ingredients. For consideration, the following information must be supplied: 1. The diagnosis requiring therapy. 2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.

Iowa Medicaid Drug Prior Authorization Criteria

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Short Acting Opioids *Use Short Acting Opioids PA form*	Prior authorization(PA) is required for all non-preferred short acting opioids. PA is also required for members when the total daily dose (combined across all opioids) exceeds the set morphine milligram equivalent (MME) threshold (include High Dose Opioids PA form with request). Payment will be considered under the following conditions: 1. Patient has pain severe enough to require opioid treatment; and 2. Patient has tried and failed at least two non-pharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and 3. Patient has tried and failed at least two non-opioid pharmacologic therapies (e.g. acetaminophen or NSAIDs); and 4. Patient has documentation of previous trials and therapy failures with three (3) chemically distinct preferred short acting opioids (based on opioid ingredient only) at therapeutic doses; and 5. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website and has determined that use of a short-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and 6. Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids; and 7. For patients taking concurrent benzodiazepines, the prescriber must document the following: a. The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and b. Documentation as to why concurrent use is medically necessary is provided; and c. A plan to taper the benzodiazepine is provided, if appropriate. If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met: 1. Patient has experienced improvement in pain control and level of functioning; and 2. Prescriber has reviewed the patient's use of controlled substances on the Iowa PMP website and has determined continued use of a short-acting opioid is appropriate for this member; and 3. For patients taking concurrent benzodiazepines, the prescriber must document the following: a. The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and b. Documentation s to why concurrent use is medically necessary is provided; and c. A plan to taper the benzodiazepine is provided, if appropriate. The required trials may be overridden when documented evidence is provided that use of these agents and/or non-pharmacologic therapies would be medically contraindicated.

For all drugs requiring prior authorization, in the event of an emergency situation when a prior authorization request cannot be submitted and a response received within 24 hours such as after regular working hours or on weekends, a 72-hour supply of the drug may be dispensed and reimbursement will be made, unless otherwise noted in criteria. Certain drugs are allowed a 7 day supply while prior authorization is being requested. PDL IMPLEMENTATION DATE 01-15-05

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Sodium Oxybate (Xyrem®) *Use Sodium Oxybate (Xyrem®) PA form*	Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered under the following conditions: 1. A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline; or 2. A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant; and 3. Patient meets the FDA approved age; and 4. Is prescribed within the FDA approved dosing; and 5. Patient and prescriber are enrolled in the Xyrem® REMS Program; and 6. Patient has been instructed to not drink alcohol when using Xyrem; and 7. Patient has been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence; and 8. Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered. 9. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website prior to requesting prior authorization. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
Step Therapy Requirements *Use Non-Preferred Drug PA form*	Designated therapeutic drug classes are subject to step therapy edits. For these therapeutic drug classes, drugs are assigned to numbered steps and appropriate trials must be made of the drugs assigned to each step before payment will be made for drugs assigned to a subsequent step. These therapeutic classes, as well as the specific step edit requirements, are identified on the Iowa Medicaid Preferred Drug List posted on the website www.iowamedicaidpdl.com under the Preferred Drug Lists tab. Providers should submit a Prior Authorization request for override consideration. Therapeutic Classes Included: Antipsychotics-Atypicals
Tasimelteon (Hetlioz®) *Use Tasimelteon (Hetlioz®) PA form*	Prior authorization is required for tasimelteon (Hetlioz®). Requests for doses above the manufacturer recommended dose will not be considered. Payment will be considered under the following conditions: 1. Patient has a diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), as confirmed by a sleep specialist; and 2. Patient is 18 years of age or older; and 3. Documentation the patient is totally blind with no perception of light is provided; and 4. Patient has a documented trial and therapy failure with at least one preferred sedative/hypnotic-non-benzodiazepine agent; and 5. Patient has a documented trial and therapy failure with ramelteon (Rozerem®). If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered when the patient has received 3 months of continuous therapy and patient has achieved adequate results with tasimelteon (Hetlioz®), such as entrainment, significant increases in nighttime sleep, and/or significant decreases in daytime sleep.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Testosterone Products *Use Testosterone Products PA form*	Prior authorization is required for testosterone products. Payment will be considered with documentation of a specific testicular or hypothalamic/pituitary disease (primary hypogonadism or hypogonadotropic hypogonadism) that results in classic hypogonadism. Requests for FDA approved indications other than hypogonadism will not be subject to prior authorization criteria with adequate documentation of diagnosis. Payment for non-preferred testosterone products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred agents. Requests for erectile dysfunction, infertility, and age-related hypogonadism will not be considered. Payment will be considered under the following conditions: 1. Patient is male and 18 years of age or older (or 12 years of age or older for testosterone cypionate); and 2. Patient has two (2) morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used (please attach lab results); and 3. Patient has primary hypogonadism or hypogonadotropic hypogonadism (further defined below): a. Primary hypogonadism (congenital or acquired) caused by testicular failure due to one of the following: • Cryptorchidism • Bilateral torsion • Orchitis • Vanishing testes syndrome • Orchiectomy • Klinefelter's syndrome • Chemotherapy • Toxic damage from alcohol or heavy metals b. Hypogonadotropic hypogonadism • Idiopathic gonadotropin or luteinizing hormone-releasing (LHRH) deficiency • Pituitary-hypothalamic injury from tumors, trauma, or radiation 4. Patient does not have: a. Breast or prostate cancer b. Palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL c. Hematocrit > 50% d. Untreated severe obstructive sleep apnea e. Severe lower urinary tract symptoms f. Uncontrolled or poorly controlled heart failure If criteria for coverage are met, initial authorization will be given for 3 months. Requests for continuation of therapy will require the following: 1. An updated testosterone level (Please attach lab result); and 2. Documentation the patient has not experienced a hematocrit > 54% or an increase in PSA > 1.4ng/mL in the past 12 months. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Tezacaftor/Ivacaftor (Symdeko) *Use Tezacaftor/Ivacaftor (Symdeko) PA form*	Prior authorization is required for Symdeko (tezacaftor/ivacaftor). Payment will be considered for patients when the following criteria are met: 1. Patient meets the FDA approved age; and 2. Patient has a diagnosis of cystic fibrosis (CF)*;* and 3. Patient is homozygous for the F508del mutation or patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor (listed in the FDA approved labeling) based on *in vitro* data and/or clinical evidence. 4. Prescriber is a CF specialist or pulmonologist; and 5. Baseline liver function tests (AST/ALT) are provided. If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met: 1. Adherence to tezacaftor/ivacaftor therapy is confirmed; and 2. Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.
Topical Acne and Rosacea Products *Use Topical Acne and Rosacea Products PA form*	Prior authorization (PA) is required for topical acne agents (topical antibiotics and topical retinoids) and topical rosacea agents. Payment for topical acne and topical rosacea agents will be considered under the following conditions: 1. Documentation of diagnosis. 2. For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid. 3. Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid). 4. Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent. 5. Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products. 6. Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis. 7. Trial and therapy failure with a preferred topical antipsoriatic agent will not be required for the preferred tazarotene (Tazorac) product for a psoriasis diagnosis. 8. Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Updated 7/1/2019

Topical Antifungals for Onychomycosis *Use Topical Antifungals for Onychomycosis PA form*	Jublia (efinaconazole) and Kerydin (tavaborole) will be considered when the following criteria are met: 1. Patient has a diagnosis of onychomycosis of the toenail(s) confirmed by a positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy (attach results) without dermatophytomas or lunula (matrix) involvement; and 2. Patient is 18 years of age or older; and 3. Patient has documentation of a complete trial and therapy failure or intolerance to oral terbinafine; and 4. Patient has documentation of a complete trial and therapy failure or intolerance to ciclopirox 8% topical solution; and 5. Patient is diabetic or immunosuppressed/immunocompromised. If the criteria for coverage are met, a one-time authorization of 48 weeks will be given. Requests for reoccurrence of infection will not be considered The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.
Topical Corticosteroids *Use Topical Corticosteroids PA form*	Prior authorization is required for non-preferred topical corticosteroids. Payment will be considered for patients when there is documentation of adequate trials and therapy failures with at least two preferred, chemically distinct, topical corticosteroid agents within the same potency class or a higher potency class in the past 12 months. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
Valsartan/Sacubitril (Entresto) *Use Valsartan/Sacubitril (Entresto) PA form*	Prior authorization is required for valsartan/sacubitril (Entresto). Requests above the manufacturer recommended dose will not be considered. Payment will be considered for patients when the following criteria are met: 1. Patient is 18 years of age or older; and 2. Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and 3. Patient has a left ventricular ejection fraction (LVEF) ≤40%; and 4. Patient is currently tolerating treatment with an ACE inhibitor or angiotensin ll receptor blocker (ARB) at a therapeutic dose, where replacement with valsartan/sacubitril is recommended to further reduce morbidity and mortality; and 5. Is to be administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB (list medications patient is currently taking for the treatment of heart failure); and 6. Will not be used in combination with an ACE inhibitor or ARB; and 7. Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and 8. Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and 9. Patient is not pregnant; and 10. Patient does not have severe hepatic impairment (Child Pugh Class C); and 11. Prescriber is a cardiologist or has consulted with a cardiologist (telephone consultation is acceptable). The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
Vesicular Monoamine Transporter (VMAT) 2 Inhibitors	Prior authorization is required for VMAT 2 inhibitors. Payment for non-preferred agents will be considered only for cases in which there is documentation of previous trial and therapy failure with a preferred agent (when applicable, based on diagnosis). Payment will be considered under the following conditions: <u>Tardive Dyskinesia</u> (Ingrezza or Austedo) 1. Patient meets the FDA approved age; and 2. Patient has a diagnosis of tardive dyskinesia (TD) based on the presence of ALL of the following:

	a. Involuntary athetoid or choreiform movements b. Documentation or claims history of current or prior chronic use (≥ 3 months or 1 month in patients ≥ 60 years old) of a dopamine receptor blocking agent (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.) c. Symptoms lasting longer than 4-8 weeks; and 3. Prescribed by or in consultation with a neurologist or psychiatrist; and 4. Prescriber has evaluated the patient's current medications for consideration of a dose reduction, withdrawal, or change of the dopamine receptor blocking agent causing the TD; and 5. Documentation of baseline AIMS (Abnormal Involuntary Movement Scale) Score (attach AIMS); and 6. For Ingrezza: a. Will not be used concurrently with MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); and b. Will not be used concurrently with other vesicular monoamine transporter 2 (VMAT2) inhibitors; and c. Is prescribed within the FDA approved dosing; or 7. For Austedo: a. Patient is not suicidal, or does not have untreated/inadequately treated depression; b. Patient does not have hepatic impairment; c. Will not be used concurrently with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and d. Patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed 36mg per day (18mg twice daily); and e. Is prescribed within the FDA approved dosing. If criteria for coverage are met, initial requests will be given for 3 months. Continuation of therapy will be considered when the following criteria are met: 1. Patient continues to meet the criteria for initial approval; and 2. Documentation of improvement in TD symptoms as evidenced by a reduction of AIMS score from baseline (attach current AIMS). <u>Chorea associated with Huntington's disease</u> (Austedo or tetrabenazine) 1. Patient meets the FDA approved age; and 2. Patient has a diagnosis of Huntington's disease with chorea symptoms; and 3. Prescribed by or in consultation with a neurologist or psychiatrist; and 4. Is prescribed within the FDA approved dosing; and 5. Patient is not suicidal, or does not have untreated or inadequately treated depression; and 6. Patient does not have hepatic impairment; and 7. Patient does not have concurrent therapy with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Duplicate use of drugs from the same therapeutic category or therapeutic duplication will not be considered**.** All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure. The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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Use Vesicular Monoamine Transporter (VMAT) 2 Inhibitors PA form	8. For tetrabenazine, patients requiring doses above 50mg per day have been tested and genotyped for the drug metabolizing enzyme CYP2D6 to determine if they are a poor metabolizer or extensive metabolizer; and 9. In patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed the following: a. Austedo - 36mg per day (18mg single dose) or b. Tetrabenazine – 50mg per day (25mg single dose) If criteria for coverage are met, initial requests will be given for 3 months. Continuation of therapy will be considered when the following criteria are met: 1. Patient continues to meet the criteria for initial approval; and 2. Documentation of improvement in chorea symptoms is provided.
Vitamins, Minerals and Multiple Vitamins *Use Vitamin/Mineral PA form*	Payment for vitamins, minerals and multiple vitamins for treatment of specific conditions will be approved when there is a diagnosis of specific vitamin or mineral deficiency disease or for patients under 21 years of age if there is a diagnosed disease which inhibits the nutrition absorption process as a secondary effect of the disease. (Prior approval is not required for prescribed multi-vitamins with or without iron or vitamin D supplements for patients under 12 months of age or a prescription product primarily classified as a blood modifier, if that product does not contain more than three vitamins/minerals or for products principally marketed as prenatal vitamin-mineral supplements.)
Vorapaxar (Zontivity) *Use Vorapaxar (Zontivity) PA form*	Prior authorization is required for vorapaxar (Zontivity). Payment will be considered under the following conditions: 1. Patient has a history of myocardial infarction (MI) or peripheral artery disease (PAD); and 2. Patient does not have a history of stroke, transient ischemic attack (TIA), intracranial bleeding, or active peptic ulcer; and 3. Patient has documentation of an adequate trial and therapy failure with aspirin plus clopidogrel; and 4. Patient will use vorapaxar concurrently with aspirin and/or clopidogrel. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.