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 3/1/2017

ADD/ADHD/ NARCOLEPSY AGENTS *Use CNS Stimulants and Atomoxetine PA form*	*See CNS Stimulants and Atomoxetine Prior Authorization Criteria.*
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 4. Previous trial and therapy failure at a therapeutic dose with atomoxetine (Strattera®). 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 3/1/2017

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 • 80mg/dl if measured by radial immunodiffusion, or • 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.

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 3/1/2017

Angiotensin Receptor Blocker Before ACE Inhibitor *Use Angiotensin Receptor Blocker Before ACE Inhibitor PA form*	Payment for Angiotensin Receptor Blockers (ARB) and Angiotensin Receptor Blocker Combinations will only be considered for cases in which there is a contraindication or therapy failure with at least one ACE-I or ACE-I Combination. A completed prior authorization form will need to be submitted if a trial with an ACE-I or ACE-I Combination of at least 30 days in length is not found in the point-of-sale system and/or unless evidence is provided that use of an ACE-I or ACE-I Combination would be medically contraindicated. Prior authorization is required for all non-preferred ARBs and ARB Combinations the first day of therapy. Payment for a non-preferred ARB or ARB Combination will be considered following documentation of recent trials and therapy failures with a preferred ACE-I or ACE-I Combination AND a preferred ARB or ARB Combination.
Antidepressants *Aplenzin* *Brintellix* *Fetzima* *Khedezla* *Pristiq* *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, unless evidence is provided that use of this agent would be medically contraindicated. 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 and a preferred Incretin Mimetic at maximally tolerated doses, unless 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.

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 3/1/2017

<table>
<tr><td>Antiemetic-5HT3 Receptor Antagonists/ Substance P Neurokinin Agents

Use Antiemetic-5HT3 Receptor Antagonists/ Substance P Neurokinin Agents form</td><td>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)</td></tr>
<tr><td>Anti-Fungal

Use Anti-Fungal PA form</td><td>Prior authorization is not required for preferred oral antifungal therapy for a cumulative 90 days of therapy per 12-month period per patient. Prior authorization will be required for all non-preferred oral antifungal therapy beginning the first day of therapy. Payment for a non-preferred oral 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 oral 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.</td></tr>
</table>

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 3/1/2017

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.
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. Prescribed by a rheumatologist or a dermatologist; and 5. Patient does not have severe renal impairment (CrCl < 30 mL/min). <u>Psoriatic Arthritis</u> • 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 • Patient has documentation of trials and therapy failures with two preferred biological agents used for psoriatic arthritis. <u>Plaque Psoriasis</u> • Patient has documentation of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine; and • Patient has documentation of trials and therapy failures with two preferred biological agents. 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: Wound has decreased in size by 30% after 10 weeks

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.

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 3/1/2017

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.
Biologicals for Ankylosing Spondylitis *Adalimumab (Humira)* *Certolizumab Pegol (Cimzia)* *Etanercept (Enbrel)* *Infliximab (Remicade)* *Golimumab (Simponi)* *Use Biologicals for Ankylosing Spondylitis PA form*	Prior authorization is required for biologicals used for ankylosing spondylitis. 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. 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; 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 biological agent; 3. 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 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 following inadequate responses 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. 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. 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 3/1/2017

Biologicals for Arthritis *Abatacept (Orencia)* *Adalimumab (Humira)* *Anakinra (Kineret)* *Certolizumab Pegol (Cimzia)* *Etanercept (Enbrel)* *Infliximab (Remicade)* *Golimumab (Simponi)* *Tocilizumab (Actemra)* *Ustekinumab (Stelara)* *Use Biologicals for Arthritis PA form*	Prior authorization is required for biologicals used for arthritis. 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; 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 biological agent; 3. 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 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. 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, leflunomide,or minocycline). 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. 2. 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). 3. 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). The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of a previous trials and therapy failures with two preferred biological agents.

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 3/1/2017

Biologicals for Inflammatory Bowel Disease *Adalimumab (Humira)* *Certolizumab Pegol (Cimzia)* *Golimumab (Simponi)* *Infliximab (Remicade)* *Use Biologicals for Inflammatory Bowel Disease PA form*	Prior authorization is required for biologicals used for inflammatory bowel disease. 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. 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; 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 biological agent; 3. 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 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: • 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. • Ulcerative colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine. 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 3/1/2017

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.

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 3/1/2017

Biologicals for Plaque Psoriasis *Alefacept (Amevive)* *Adalimumab (Humira)* *Etanercept (Enbrel)* *Infliximab (Remicade)* *Secukinumab (Cosentyx)* *Ustekinumab (Stelara)* *Use Biologicals for Plaque Psoriasis PA form*	Prior authorization is required for biologicals used for plaque psoriasis. 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. 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; 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 biological agent; 3. 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 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 following an inadequate response to phototherapy, systemic retinoids (oral isotretinoin), methotrexate, or cyclosporine. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
Buprenorphine Transdermal System (Butrans) & Buccal Film (Belbuca) *Butrans* *Belbuca* *Use Buprenorphine Transdermal System (Butrans) and Buccal Film (Belbuca) PA form*	Prior authorization is required for Butrans and Belbuca. Payment will be considered when the following conditions are met: 1. Previous trials and therapy failures at a therapeutic dose with two long acting opioids. The preferred trials must allow for adequate dose titration and show use of a short acting narcotic for breakthrough pain. 2. A trial and therapy failure with fentanyl patch at maximum tolerated dose. The required trials may be overridden when documented evidence it 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 3/1/2017

Buprenorphine/ Naloxone *Use Buprenorphine/ Naloxone PA form*	Prior authorization is required for buprenorphine or buprenorphine/naloxone. Requests for doses above 24mg per day or greater than once daily dosing 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. Concomitant use with opioids, tramadol and hypnotics will be prohibited. Benzodiazepines will be allowed up to a cumulative 30 days per 12 month period. 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 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 is 16 years of age or older: AND 2. Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number; AND 3. Patient is participating in and compliant with formal substance abuse counseling/psychosocial therapy: AND 4. A projected treatment plan is provided, including: ▪ Anticipated induction/stabilization dose, ▪ Anticipated maintenance dose, ▪ Expected frequency of office visits, and ▪ Expected frequency of counseling/psychosocial therapy visits. 5. Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant. 6. Requests for buprenorphine will only be considered for pregnant patients. Requests for renewal must include: ▪ An updated treatment plan, including consideration of a medical taper to the lowest effective dose based on a self-assessment scale, ▪ Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances since the last prior authorization request, ▪ Documentation of a current, negative drug screen, ▪ Documentation the patient has been compliant with office visits and counseling/psychosocial therapy visits. ▪ Documentation the patient is not using transmucosal buprenorphine with the buprenorphine implant.

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 3/1/2017

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: o 3-beta-hydroxy-delta-5C27-steroid oxidoreductase deficiency (3β-HSD), o aldo-keto reductase 1D1 (AKR1D1), o alpha-methylacyl-CoA racemase deficiency (AMACR deficiency), o sterol 27-hydroxylase deficiency (cerebrotendinous xanthomatosis [CTX]), o cytochrome P450 7A1 (CYP7A1), o 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: • Body weight has increased by 10% or is stable at ≥50th percentile, • Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 50 U/L or baseline levels reduced by 80%, • 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 3/1/2017

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. There must be a significant decrease in opioid use or discontinuation of opioid(s) after the initial three (3) month authorization for further approval consideration. Additional prior authorizations will be considered with documentation of a continued decrease in opioid utilization. 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, duloxetine or topical lidocaine. 4. A diagnosis of partial onset seizures, as adjunct therapy (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 at https://pmp.iowa.gov/IAPMPWebCenter/. Payment for CNS stimulants and atomoxetine will be considered under the following conditions: 1. Attention Deficit Disorder (ADD) or 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 the patient continues to require medication to treat the symptoms of ADD/ADHD will be required for renewals or patients newly eligible that are established on medication to treat ADD/ADHD. 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.

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 3/1/2017

4. Binge Eating Disorder (Vyvanse only)
   - Patient is 18 to 55 years of age; and
   - Patient meets DSM-5 criteria for Binge Eating Disorder (BED); and
   - 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
   - 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
   - Prescription is written by a psychiatrist or psychiatric nurse practitioner; and
   - Patient has a BMI of 25 to 45; and
   - Patient does not have a history of cardiovascular disease; and
   - Patient has no history of substance abuse; and
   - Is not being prescribed for the treatment of obesity or weight loss; and
   - Doses above 70mg per day will not be considered.
   - Initial requests will be approved for 12 weeks.
   - 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

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 CNS Stimulants and Atomoxetine or Binge Eating Disorder Agents PA form	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 immediate release and 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.
Colchicine *Use Colchicine PA form*	Prior authorization is not required for Mitigare® for the treatment of acute gout for three (3) tablets per 60-day period. Prior authorization is required for all colchicine products for the treatment of chronic hyperuricemia/gout prophylaxis or Familial Mediterranean fever. Payment will be considered under the following conditions: 1. Chronic hyperuricemia/gout prophylaxis following a trial and therapy failure at a therapeutic dose with allopurinol or probenecid. A quantity limit of sixty (60) tablets per thirty (30) days will be applied, when criteria for coverage are met. 2. Familial Mediterranean fever. A maximum quantity of 120 tablets per thirty (30) days will be applied for this diagnosis. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
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.
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.

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Deferasirox (Exjade®)	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-
Use Deferasirox (Exjade®) PA form	

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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	10mg/kg/day (if LIC is 3 to 7 mg Fe/g dw) or 20mg/kg/day (if LIC is > 7mg Fe/g dw).
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.*
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.

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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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. Known or suspected biliary duct obstruction, or sphincter of Oddi disease/dysfunction. b. Alcoholism, alcohol abuse, alcohol addiction, or consumption of more than 3 alcoholic beverages per day. c. A history of pancreatitis or structural diseases of the pancreas (including known or suspected pancreatic duct obstruction). d. Severe hepatic impairment (Child-Pugh Class C). e. Severe constipation or sequelae from constipation. f. 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.

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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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, Amrix, Astagraf XL, Augmentin XR, Cardura XL, Cipro XR, Conzip ER, Coreg CR, Doryx, Flagyl ER, Fortamet, Gralise, Keppra XR, Lamictal XR, Luvox CR, Metronidazole SR, Mirapex ER, Moxatag, Namenda XR, Oleptro, Oxtellar XR, Pramipexole ER, Prozac Weekly, Qudexy XR, Rayos, Requip XL, Rythmol SR, Ryzolt, Seroquel XR, Sitavig, Solodyn ER, Topiramate ER, Tramadol SR, Trokendi XR, Ultram ER.
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.

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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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: • 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. • 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.
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.
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.

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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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.
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 is 18 years of age or older and has a diagnosis of chronic hepatitis C; and 2. Patient has had testing for hepatitis C virus (HCV) genotype; and 3. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and 4. Viral load will be submitted by prescriber 12 weeks after completion of therapy; and 5. Patient has advanced liver disease corresponding to a Metavir score of 3 or greater fibrosis as confirmed by one of the following: ▪ Liver biopsy confirming Metavir score ≥ F3; or ▪ Transient elastography (FibroScan) score ≥ 9.5kPa; or ▪ FibroSURE (FibroTest) score ≥ 0.58; or ▪ APRI score > 1.5; or ▪ Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); or ▪ Physical findings or clinical evidence consistent with cirrhosis; or ▪ 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. 6. Patient's prior treatment history is provided (treatment naïve or treatment experienced); 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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	7. 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 8. 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 9. For regimens containing sofosbuvir, patient does not have severe renal impairment (creatinine clearance < 30ml/min) or end stage renal disease requiring hemodialysis; and 10. HCV treatment is prescribed by a digestive disease, liver disease, or infectious disease provider practice; and. 11. 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 12. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication. 13. Documentation is provided for patients who are ineligible to receive ribavirin. 14. Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved. 15. 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.
Use Hepatitis C Treatments PA form	16. Lost or stolen medication replacement requests will not be authorized. 17. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

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 3/1/2017

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): • Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or • 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: • Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or • Pifenidone - Patient does not have severe hepatic impairment (Child Pugh C); and 8. Patient does not have renal impairment as defined below: • Nintedanib - Patient does not have severe renal impairment (CrCl <30ml/min) or end-stage renal disease or • 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.

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Updated 3/1/2017

Immunomodulators-Topical *Elidel®* *Protopic®* *Use Immunomodulators-Topical PA form*	Prior authorization is required for topical immunomodulators. 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 two preferred topical corticosteroids. 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.
Insulin, Pre-Filled Pens *Use Pre-filled Insulin Pen PA form*	Prior authorization is required for pre-filled insulin pens. Prior authorization is granted when documentation indicates: • 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 • There is no caregiver available to provide assistance. • Patient does not reside in a long-term care facility. Prior authorization for non-preferred insulin pens will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent.
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

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Updated 3/1/2017

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 is 2 years of age or older; and 2. Has a diagnosis of cystic fibrosis with one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, and R117H as detected by a FDA-cleared CF mutation test; and 3. Prescriber is a CF specialist or pulmonologist; and 4. Baseline liver function tests (AST/ALT) and FEV_1, if age appropriate, are provided; and 5. Patient does not have one of the following infections: *Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abcessus*. 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. Response to therapy is documented by prescriber (e.g., improved FEV_1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and 3. Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.

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 3/1/2017

Janus Kinase Inhibitors *Use Janus Kinase Inhibitor PA form*	Prior authorization is required for Janus kinase (JAK) inhibitors. Payment will be considered when the following conditions are met: 1. The patient is 18 years of age or older: and 2. Has a diagnosis of moderate to severe rheumatoid arthritis; and 3. Has 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, leflunomide, or minocycline); and 4. Has a documented trial and inadequate response to two preferred biological DMARDs; and 5. The patient is not using or planning to use tofacitinib in combination with biologic DMARDs or potent immunosuppressants (azathiorpine or cyclosporine); and 6. Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and 7. Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to the manufacturer labeling; and 8. Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and 9. Patient is not at an increased risk of gastrointestinal perforation. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
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.
Lidocaine Patch (Lidoderm®) *Use Lidocaine Patch (Lidoderm®) PA form*	Prior authorization is required for topical lidocaine patches (Lidoderm®). Payment will be considered for a diagnosis of pain associated with post-herpetic neuralgia following a previous treatment failure with a preferred agent at therapeutic dose from two of the following: tricyclic antidepressant, opioid, gabapentin, carbamazepine, or valproic acid. A maximum of 30 patches may be dispensed with the initial prescription to determine efficacy.

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Updated 3/1/2017

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: • Vancomycin-resistant Enterococcus (VRE) and no alternatice regimens with documented efficacy are available and VRE is not in lower urinary tract**. • Methicillin-resistant Staph aureus (MRSA) and patient is intolerant to vancomycin* • Methicillin-resistant Staph epidermis (MRSE) and patient is intolerant to vancomycin* *Severe intolerance to vancomycin is defined as: – Severe rash, immune-complex mediated, determined to be directly related to vancomycin administration – 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.

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 3/1/2017

Long-Acting Opioids *Use Long-Acting Opioids PA form*	Prior authorization is required for all non-preferred long-acting opioids. 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 (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 website at https://pmp.iowa.gov/IAPMPWebCenter/ 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. 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 Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ and has determined continued use of a long-acting opioid is appropriate for this member. 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 3/1/2017

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 is 12 years of age or older; 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. Baseline percent predicted forced expiratory volume ($ppFEV_1$) is provided and is greater than or equal to (≥) 40; and 6. Prescriber is a CF specialist or pulmonologist; and 7. Patient does not have one of the following infections: *Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abcessus*. 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. Response to therapy is documented by prescriber (e.g., improved $ppFEV_1$ from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and 3. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.

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 3/1/2017

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: • 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. • Uterine leiomyomata – 3 month approval. • 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 3/1/2017

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.

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Updated 3/1/2017

Mepolizumab (Nucala) *Use Mepolizumab (Nucala) PA form*	Prior authorization is required for mepolizumab (Nucala). Requests will not be considered with concurrent use of omalizumab. Payment will be considered under the following conditions: 1. Patient is 12 years of age or older; and 2. Patient has a diagnosis of severe asthma with an eosinophilic phenotype; and 3. Patient has a pretreatment blood eosinophil count of ≥150 cells per mcL within the previous 6 weeks or blood eosinophils of ≥300 cells per mcL within 12 months prior to initiation of therapy; and 4. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (long-acting beta2-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and 5. Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus an LABA and LTRA; and 6. A pretreatment forced expiratory volume in 1 second (FEV_1) <80% predicted; and 7. Prescriber is an allergist, immunologist, or pulmonologist; and 8. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility. If criteria for coverage are met, an initial authorization will be given for 3 months to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered if one or more of the following criteria are met: 1. Patient continues to receive therapy with an ICS, LABA and LTRA; and 2. Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath; or 3. Patient has experienced a decrease in administration of rescue medication (albuterol); or 4. Patient has experienced a decrease in exacerbation frequency; or 5. Patient has experienced an increase in predicted FEV_1 from the pretreatment baseline. 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 3/1/2017

Methotrexate Injection *Otrexup™* *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, minocycline 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.
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.
Milnacipran (Savella) *Use Chronic Pain Syndromes PA form*	*See Chronic Pain Syndromes Prior Authorization Criteria.*

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Updated 3/1/2017

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, Metozolv ODT, Remeron SolTab, Risperdal M-Tab, Spritam, Trilipix, Xopenex, Zyprexa Zydis.
Multiple Sclerosis Agents-Oral *Use Multiple Sclerosis Agents-Oral PA form*	Prior authorization is required for fingolimod (Gilenya™), teriflunomide (Aubagio®), or dimethyl fumarate (Tecfidera™). Payment will be considered for patients 18 years of age and older under the following conditions: 1. A diagnosis of relapsing forms of multiple sclerosis; and 2. A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis. 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™), documentation of the following must be provided: • 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. • 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. • Patient does not have a baseline QTc interval ≥ 500ms. • Patient is not being treated with Class la or Class lll anti-arrythmic drugs. For patients initiating therapy with teriflunomide (Aubagio®), documentation of the following must be provided: • Patient does not have severe hepatic impairment. • A negative pregnancy test for females of childbearing age. • Use of a reliable form of contraception for females of childbearing age. • Patient is not taking leflunomide. For patients initiating therapy with dimethyl fumarate (Tecfidera™), documentation of the following must be provided: • Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy. • Upon renewal, documentation of an updated CBC.

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Updated 3/1/2017

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.
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.

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 3/1/2017

Nicotine Replacement Therapy *Use Nicotine Replacement Therapy PA form*	Prior Authorization is required for over-the-counter nicotine replacement patches, gum, or lozenges, and prescription nicotine nasal spray or inhaler. Requests for authorization must include: 1) Diagnosis of nicotine dependence and referral for counseling 1) to Quitline Iowa program for Medicaid Fee-for service members or 2) through the Managed Care Organization program for managed care members. 2) Confirmation of enrollment in the counseling program is required for approval. Continuation therapy is available only with documentation of ongoing participation in the counseling program. 3) Approvals will only be granted for patients eighteen years of age and older. 4) The maximum allowed duration of therapy is twelve weeks total combined therapy within a twelve-month period. 5) Patients may receive nicotine replacement patches in combination with one of the oral nicotine replacement products (gum or lozenges). A maximum quantity of 14 nicotine replacement patches and 110 pieces of nicotine gum or 144 nicotine lozenges may be dispensed with the initial prescription. Subsequent prescription refills will be allowed to be dispensed as a 4 week supply at one unit per day of nicotine replacement patches and 330 pieces of nicotine gum or 288 nicotine lozenges. 6) Requests for non-preferred nicotine replacement products will be considered after documentation of previous trials and intolerance with a preferred oral and preferred topical nicotine replacement product. A maximum quantity of 168 nicotine inhalers or 40ml nicotine nasal spray may be dispensed with the initial prescription. Subsequent prescription refills will be allowed to be dispensed as a 4 week supply at 336 nicotine inhalers or 80ml of nicotine nasal spray. 7) The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation.
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.

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 3/1/2017

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 topical nsaid must document previous trials and therapy failures with three preferred nsaids. The trials must include two preferred COX-2 preferentially selective nsaids and the oral drug of the same chemical entity. In addition, the use of a topical delivery system must be deemed medically necessary. 4. 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.
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.

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 3/1/2017

Omalizumab (Xolair®) *Use Xolair® PA form*	Prior authorization is required for Xolair®. Payment for Xolair® will be authorized when the following criteria are met: Moderate to Severe Persistent Asthma 1. Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and 2. Patient is 12 years of age or older; and 3. Pretreatment IgE level is between 30 IU/mL and 700 IU/mL; and 4. Patient's weight is between 30 kg and 150 kg; and 5. History of positive skin or RAST test to a perennial aeroallergen; and 6. Prescriber is an allergist, immunologist, or pulmonologist; and 7. Patient is currently using a high dose inhaled corticosteroid AND long-acting beta-agonist, is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy. 8. Patient must have access to an EpiPen to treat allergic reactions that may occur after administration of Xolair®. If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to Xolair® therapy and for patients who do not continue concurrent use with a high dose corticosteroid and long-acting beta-agonist. Chronic Idiopathic Urticaria 1. Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and 2. Patient is 12 years of age or older; and 3. Patient has documentation of a trial and therapy failure with at least one second-generation antihistamine, one of which must be cetirizine at a dose up to 20mg per day; and 4. Patient has documentation of a trial and therapy failure with at least one first-generation antihistamine; and 5. Patient has documentation of a trial and therapy failure with at least one potent H1 receptor antagonist (hydroxyzine and/or doxepin) and: 6. Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second- generation antihistamine. If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy. 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 3/1/2017

Oral Constipation Agents *Use Oral Constipation Agents PA form*	Prior authorization is required for lubiprostone (Amitiza®), linaclotide (Linzess™) and naloxegol (Movantik™). Payment will be considered under the following conditions: 1. Patient is 18 years of age or older; and 2. Patient must have documentation of adequate trials and therapy failures with at least one medication from each of the following categories: a. Saline laxative (milk of magnesia); and b. Osmotic laxative (polyethylene glycol or lactulose); and c. Stimulant laxative (senna); 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® or Linzess™) 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® or Linzess™) i. Patient is female (Amitiza® only); and ii. Patient has abdominal pain or discomfort at least 3 days per month in the last 3 months associated with two (2) or more of the following: 1. Improvement with defecation; 2. Onset associated with a change in stool frequency; and/or 3. Onset associated with a change in stool form c. A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza® or Movantik™) 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.

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 3/1/2017

Oral Immunotherapy *Grastek®* *Ragwitek®* *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 conrticosteroids 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> • Patient is 18 through 65 years of age; and • Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to short ragweed pollen. • 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® • Patient is 10 through 65 years of age; and • 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. • 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® • Patient is 5 through 65 years of age; and • 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). • 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 3/1/2017

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. • 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. • 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. • 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> • 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). • 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> • 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> • 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> • 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> • 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 3/1/2017

PCSK9 Inhibitors *Praluent*® *Repatha*™	Prior authorization is required for PCSK9 Inhibitors. 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>

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 3/1/2017

	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 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. <u>Initial and Renewal Authorizations</u> <u>HeFH or ASCVD</u> • Initial o Praluent 75mg or Repatha 140mg every 2 weeks for 8 weeks (4 doses). • Renewal o Lipid profile required at week 8, week 24, and every 6 months thereafter; and o Patient continues therapy with a maximally tolerated statin dose and remains at goal; and o Patient has continued compliance with a low fat diet; and <u>Praluent</u> o If LDL-C at goal, continue therapy at 75mg every 2 weeks for 24 weeks. o 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. ▪ If repeat LDL-C not at goal, discontinue Praluent. ▪ If repeat LDL-C at goal, continue therapy at 150mg every 2 weeks for 24 weeks; or <u>Repatha</u> o If LDL-C at goal, continue therapy at 140mg every 2 weeks for 24 weeks. o If LDL-C not at goal, discontinue Repatha.

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 3/1/2017

Use PCSK9 Inhibitors PA form	<u>HoFH (Repatha only)</u>
	• Initial
	  ○ Repatha 420mg (3x140mg autoinjectors) every month for 3 months.
	• Renewal
	  ○ Lipid profile required after 3 months (third dose) and every 6 months thereafter; and
	  ○ Continued therapy with a maximally tolerated statin dose.
	  ▪ If LDL-C at goal, continue therapy at 420mg every month for six months.
	  ▪ If LDL-C not at goal, discontinue Repatha*;* and
	  ○ Patient has continued compliance with a low fat diet.
	
	<u>Quantity Limits</u>
	Praluent/Repatha for HeFH or ASCVD
	• A quantity limit of one syringe/pen/autoinjector per fill will apply (requires refill every 14 days).
	Repatha for HoFH only
	• A quantity limit of one three-pack per month

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.*

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 3/1/2017

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 for a diagnosis of 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. Requests for twice daily dosing for a diagnosis of 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
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.

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 3/1/2017

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.

Updated 3/1/2017

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.
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.

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 3/1/2017

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. Brand/generic and all dosage forms of the following agents are subject to this criteria: Afinitor, Alecensa, Bosulif, Cabometyx, Cotellic, Erbitux, Erivedge, Gilotrif, Gleevec, Herceptin, Hycamtin, Hydroxyprogesterone Caproate, Ibrance, Imbruvica, Inlyta, Istodax, Lonsurf, Lynparza, Mekinist, Nexavar, Ninlaro, Odomzo, Pomalyst, Revlimid, Sprycel, Stivarga, Sutent, Tafinlar, Tagrisso, Tarceva, Tasigna, Temodar, Tretinoin (chemotherapy), Tykerb, Venclexta, Votrient, Xalkori, Xeloda, Zelboraf, Zydelig, Zykadia.
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.
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.

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 3/1/2017

Short Acting Opioids *Use Short Acting Opioids PA form*	Prior authorization is required for all non-preferred short acting opioids. 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 (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. 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 at https://pmp.iowa.gov/IAPMPWebCenter/ and has determined continued use of a short-acting opioid is appropriate for this member. 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.
Smoking Cessation Therapy-Oral *Chantix®* *Bupropion SR* *Use Smoking Cessation Therapy-Oral PA form*	Prior Authorization is required for varenicline (Chantix®) or bupropion SR that is FDA approved for smoking cessation. Requests for authorization must include: 1) Diagnosis of nicotine dependence and referral for counseling 1) to Quitline Iowa program for Medicaid Fee-for service members or 2) through the Managed Care Organization program for managed care members. 2) Confirmation of enrollment and ongoing participation in the counseling program is required for approval and continued coverage. 3) Approvals will only be granted for patients eighteen years of age and older. 4) The duration of therapy is initially limited to twelve weeks within a twelve-month period. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment will be considered with a prior authorization request. The maximum duration of approvable therapy is 24 weeks within a twelve-month period. 5) Requests for varenicline to be used in combination with bupropion SR that is FDA indicated for smoking cessation or nicotine replacement therapy will not be approved. 6) The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation

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 3/1/2017

Sodium Oxybate (Xyrem®) *Use Sodium Oxybate (Xyrem®) PA form*	Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered for patients 18 years of age or older 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. 2. Patient is enrolled in the Xyrem® REMS Program. 3. 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. 4. Patient has been instructed to not drink alcohol when using Xyrem®. 5. Patients with and without a history of substance abuse have been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence. 6. Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered. 7. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ 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.

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 3/1/2017

Testosterone Products *Use TestosteroneProducts 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): • Primary hypogonadism (congenital or acquired) caused by testicular failure due to one of the following: o Cryptorchidism o Bilateral torsion o Orchitis o Vanishing testes syndrome o Orchiectomy o Klinefelter's syndrome o Chemotherapy o Toxic damage from alcohol or heavy metals • Hypogonadotropic hypogonadism o Idiopathic gonadotropin or luteinizing hormone-releasing (LHRH) deficiency o 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.

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.

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 3/1/2017

Thrombopoietin Receptor Agonists *Use Thrombopoietin Receptor Agonists PA form*	Payment for a preferred thrombopoietin receptor agonist will only be considered for cases in which there is a diagnosis of chronic immune thrombocytopenic purpura (ITP) including documentation of an insufficient response to a corticosteroid, an immunoglobulin, or the patient has undergone a splenectomy. Payment for eltromobopag (Promacta®) for the treatment of chronic hepatitis C associated thrombocytopenia will only be considered to allow for initiation and/or maintenance of interferon-based therapy with ribavirin when the patient has a baseline platelet count less then 75 x 10^9 L. Requests will not be considered under the following conditions: 1. Patient taking direct acting antiviral agents for the treatment of chronic hepatitis C genotype 1 infection in addition to interferon-based therapy with ribavirin. 2. Patients taking direct acting antiviral agents used without interferon for treatment of chronic hepatitis C infection. 3. Patients with decompensated liver disease with a Child-Pugh score > 6 (Class B & C). 4. Patients with a history of ascites. 5. Patients with hepatic encephalopathy. Payment for eltrombopag (Promacta®) for the treatment of severe aplastic anemia will only be considered under the following conditions: 1. Patient has documentation of an insufficient response or intolerance to at least one prior immunosuppressive therapy; and 2. Patient has a platelet count less than or equal 30 x 10^9/L. 3. 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. Payment for a non-preferred thrombopoietin receptor agonist will be considered following documentation of a recent trial and therapy failure with a preferred thrombopoietin receptor agonist unless such a trial 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 3/1/2017

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 for moderate to severe acne. 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.
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.

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 3/1/2017

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 has documentation of a previous trial and therapy failure or intolerance to an ACE inhibitor at a maximally tolerated dose; and 5. Patient has documentation of a previous trial and therapy failure or intolerance to an angiotensin II receptor blocker (ARB); and 6. 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 7. Will not be used in combination with an ACE inhibitor or ARB; and 8. Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and 9. Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and 10. Patient is not pregnant; and 11. Patient does not have severe hepatic impairment (Child Pugh Class C); and 12. 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. If the criteria for coverage are met, initial authorization will be given for 3 months. Requests for continuation of therapy may be provided if prescriber documents adequate response to therapy.
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.)

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 3/1/2017

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.
Vusion™ Ointment *Use Vusion™ Ointment PA form*	Prior Authorization is required for 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.