Iowa Medicaid Drug Prior Authorization Criteria

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. 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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ADD/ADHD/ NARCOLEPSY AGENTS *Use ADD/ADHD/Narcolepsy Agents PA form*	Prior authorization (PA) is required for ADD/ADHD/Narcolepsy agents for patients 21 years of age or older under the following conditions: 1. Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-IV 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 environments (social, academic, or occupational). 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. 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 of the preferred immediate release and extended release product of the same chemical entity is required. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
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.
Alpha$_1$-Proteinase Inhibitor Enzymes *Use Miscellaneous PA form*	Prior authorization is required for Alpha$_1$-Proteinase Inhibitor enzymes. Payment will be authorized only for cases in which there is a diagnosis of congenital alpha$_1$-proteinase inhibitor (alpha$_1$ –PI; alpha1-antitrypsin) deficiency with clinically demonstrable panacinar emphysema. 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.
Amylino Mimetic (Symlin®) *Use Amylino Mimetic (Symlin®) form*	Prior authorization is required for amylino mimetics (Symlin®). Payment will be considered under the following conditions: 1) Diagnosis of Type 1 or Type 2 diabetes mellitus, 2) Concurrent use of insulin therapy, 3) Documentation of blood glucose monitoring three or more times daily, 4) Inadequate reduction in HbgA1C despite multiple titration with basal/bolus insulin dosing regiments. Initial authorizations will be approved for six months; additional prior authorizations will be considered on an individual basis after review of medical necessity and documented improvement in HbgA1C since the beginning of the initial prior authorization period.

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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.
Anti-Acne *Use Anti-Acne PA form*	Prior authorization is required for all prescription topical acne products. Payment for the treatment of mild to moderate acne vulgaris will be considered under the following conditions: 1. Previous trial and therapy failure with a preferred over-the-counter benzoyl peroxide product, which is covered by the program without prior authorization. 2. 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. 3. If the patient presents with a preponderance of comedonal acne, topical retinoid products may be utilized as first line agents with prior authorization (use Topical Retinoids PA form). 4. Requests for non-preferred combination products may only be considered after documented separate trials and therapy failures with the individual ingredients. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.
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.

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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.
Antiemetic-5HT3 Receptor Antagonists/ Substance P Neurokinin Agents *Use Antiemetic-5HT3 Receptor Antagonists/ Substance P Neurokinin Agents form*	Prior authorization is required for preferred Antiemetic-5HT3 Receptor Antagonists/Substance P Neurokinin medications for quantities exceeding the following dosage limits per month. Payment for Antiemetic-5HT3 Receptor Agonists/ Substance P Neurokinin Agents beyond this limit will be considered on an individual basis after review of submitted documentation. Prior authorization will be required for all non-preferred Antiemetic-5HT3 Receptor Antagonists/Substance P Neurokinin medications beginning the first day of therapy. Payment for non-preferred medications will be authorized only for cases in which there is documentation of previous trial(s) and therapy failure with a preferred agent in this class. Note: Aprepitant (Emend®) will only be payable when used in combination with other antiemetic agents (5-HT3 medication and dexamethasone) for patients receiving highly emetogenic cancer chemotherapy. Aprepitant (N)/Emend® (N): 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)/Kytril®/Granisol™ (N): 8 – 1mg tablets 30mL – oral solution (1mg/5mL) 8 vials (1mg/mL) 2 vials (4mg/mL) Ondansetron (P)/Zofran® (N): 12 – 4mg tablets 12 – 8mg tablets 4 – 24mg tablets 4 – 20mL vials (2mg/mL) 8 – 2mL vials (2mg/mL) Ondansetron ODT (P)/Zofran® ODT (N): 12 – 4mg tablets 12 – 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)

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.

PDL IMPLEMENTATION DATE 01-15-05

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Anti-Fungal *Use Anti-Fungal PA form*	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.
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.
Apixaban (Eliquis®) *Use Apixaban (Eliquis®) PA form*	Prior authorization is required for apixaban (Eliquis®). Payment will be considered for patients under the following conditions: 1. Patient does not have a mechanical prosthetic heart valve; and 2. Patient does not have active pathological bleeding; and 3. Patient has a diagnosis of non-valvular atrial fibrillation; with 4. Documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial); and 5. Presence of at least one additional risk factor for stroke, with a $CHADS_2$ score ≥ 1; OR 6. For patients requiring deep vein thrombosis (DVT) prophylaxis undergoing hip or knee replacement. Requests will be considered when the patient has contraindications to use of the preferred agent(s). If patient meets criteria for coverage, requests will be approved for the following doses: • Hip replacement: 2.5mg twice daily for up to 35 days following hip replacement; or • Knee replacement: 2.5mg twice daily for up to 12 days following knee replacement The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

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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); and 3. Prescribed by a rheumatologist or a dermatologist; and 4. Patient does not have severe renal impairment (CrCl < 30 mL/min); and 5. 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 6. Patient has documentation of trials and therapy failures with two preferred biological agents used for psoriatic arthritis. 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
Benzodiazepines *Use Benzodiazepine PA form*	Prior authorization is required for non-preferred benzodiazepines. Payment for non-preferred benzodiazepines will be authorized in cases with documentation of previous trial and therapy failure with two preferred products. Requests for clobazam (ONFI) will be considered for a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older when used as an adjunctive treatment. Prior authorization will be approved for up to 12 months for documented: 1. Generalized anxiety disorder. 2. Panic attack with or without agoraphobia. 3. Seizure. 4. Non-progressive motor disorder. 5. Dystonia. If a long-acting medication is requested, one of the therapeutic trials must include the immediate release form of the requested benzodiazepine. Prior authorization requests will be approved for up to a three-month period for all other diagnoses related to the use of benzodiazepines. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

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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 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. 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.

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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.

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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. • 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.
Biologicals for Plaque Psoriasis *Alefacept (Amevive®)* *Adalimumab (Humira®)* *Etanercept (Enbrel®)* *Infliximab (Remicade®)* *Ustekinumab (Stelara®)* *Use Biologicals for Plaque Psoriasis PA form*	Prior authorization is required for biologicals used for plaque psoriasis. Payment will be considered following an inadequate response to phototherapy, systemic retinoids (oral isotretinoin), methotrexate, or cyclosporine. 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.
BRAF Inhibitors **Tafinlar®** **Zelboraf®** *Use BRAF Inhibitors PA form*	Prior authorization is required for BRAF inhibitors. Payment will be considered for patients when the following criteria are met: 1. Patient is 18 years of age or older; and 2. Has a diagnosis of unresectable or metastatic melanoma with $BRAF^{V600E}$ mutation as detected by an FDA- approved test; and 3. Prescriber is an oncologist. If the criteria for coverage are met, authorizations will be given at three (3) month intervals. Updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued.

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Buprenorphine (Butrans™) Transdermal System *Use Buprenorphine (Butrans™) Transdermal System PA form*	Prior authorization is required for Butrans™. 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.
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. 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. 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. 6. Requests for buprenorphine will only be considered for pregnant patients.

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Chronic Pain Syndromes ***Duloxetine (Cymbalta®)*** ***Pregabalin (Lyrica®)*** ***Milnacipran (Savella™)*** *Use Chronic Pain Syndromes PA form*	A prior authorization is required for duloxetine (Cymbalta®), pregabalin (Lyrica®), and milnacipran (Savella™). 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. Payment will be considered under the following conditions: 1. A diagnosis of fibromyalgia (duloxetine, Lyrica®, and Savella™) a. a trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, SSRI, or SNRI **WITH** b. documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.), **AND** c. documentation of a previous trial and therapy failure at a therapeutic dose with duloxetine when Savella™ and Lyrica® are requested. 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, valproate, orcarbamazepine. 3. A diagnosis of diabetic peripheral neuropathy (duloxetine and Lyrica®) A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant or topical lidocaine. 4. A diagnosis of partial onset seizures, as adjunct therapy (Lyrica®) 5. A diagnosis of major depressive disorder or generalized anxiety disorder (duloxetine) 6. A diagnosis of chronic musculoskeletal pain (duloxetine) A trial and therapy failure at a therapeutic dose with at least two drugs from two distinct therapeutic classes from the following: NSAIDs, opioids, tramadol, or tricyclic antidepressants. Requests for concomitant use of these agents for an indicated chronic pain diagnosis may only be considered once each agent has been tried at maximum tolerated dose separately. Duplicate use of drugs from the same therapeutic category will not be considered. Requests for doses above the manufacturer recommended dose will not be considered. Requests for non-preferred brand 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.

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Colchicine (Colcrys®) *Use Colchicine (Colcrys®) PA form*	Prior authorization is not required for colchicine (Colcrys®) for the treatment of acute gout for three (3) tablets per 60-day period. Prior authorization is required for colchicine (Colcrys®) 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. 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.
Crizotinib (Xalkori®) *Use Xalkori® PA form*	Prior authorization is required for Xalkori® (crizotinib). Payment will be considered for patients when the following is met: 1. Diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test (attach copy of results); and 2. Is prescribed by an oncologist.
Dabigatran (Pradaxa®) *Use Dabigatran (Pradaxa®) PA form*	Prior authorization is required for dabigatran (Pradaxa®). Payment will be considered for patients under the following conditions: 1. Patient does not have a mechanical prosthetic heart valve; and 2. Patient does not have active pathological bleeding; and Patient has a diagnosis of non-valvular atrial fibrillation; and 3. Documentation of a previous trial and therapy failure with warfarin (TIA, stroke, recurrence of DVT/PE, or inability to maintain a therapeutic INR with a minimum 6 month trial); and Non-valvular atrial fibrillation (in addition to the above) • Presence of at least one additional risk factor for stroke, with a $CHADS_2$ score ≥ 1; and • Patient does not have severe renal impairment (CrCl < 15mL/min) or is not on dialysis. Treatment and prevention of DVT or PE (in addition to the above) • Patient does not have a CrCl < 30mL/min or is not on dialysis • For patients with current DVT/PE, in addition to warfarin trial, patient must have documentation of 5 to 10 days of parenteral anticoagulation prior to initiation of dabigatran. 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 1/09/2015

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.
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 amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS). 2. A trial and therapy failure at a therapeutic dose with amitriptyline or an SSRI. 3. Initial authorizations will be approved for 12 weeks with a baseline Center for Neurologic Studies Lability Scale (CNS-LS) questionnaire. 4. Subsequent prior authorizations will be considered at 6 month intervals with documented efficacy as seen in an improvement in the CNS-LS questionnaire.
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.*
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.

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Updated 1/09/2015

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, Amrix, Augmentin XR, Cardura XL, Cipro XR, Coreg CR, Doryx, Flagyl ER, glipizide er, Glucotrol XL, Keppra XR, Lamictal XR, Lescol XL, Luvox CR, metronidazole sr, Mirapex ER, Moxatag, Paxil CR, Prozac Weekly, Requip XL, Ryzolt, Seroquel XR, Solodyn ER, Tegretol XR, tramadol sr, 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.
Fentanyl, Short Acting Oral Products *Use Short Acting Oral Fentanyl Products PA form*	Prior authorization is required for short acting oral 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**. Actiq®, Fentora®, & Onsolis™: • 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.

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Updated 1/09/2015

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.
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. 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). 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.

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Updated 1/09/2015

Hepatitis C Antiviral Agents ***Incivek, Olysio, Victrelis*** *Use Hepatitis C Antiviral Agents Protease Inhibitors PA form*	Prior authorization is required for direct-acting oral antiviral agents against the hepatitis C virus. 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 2. Patient's prior treatment history is provided (treatment naïve, prior null responder, partial responder, or relapser); and 3. If patient has a history of failed treatment due to non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and 4. Patient has not previously tried or failed therapy with a hepatitis C protease inhibitor; and 5. Patient is not a pregnant female or a male with a pregnant female partner; and 6. Women of childbearing potential and their male partners must use two forms of effective contraception (non-hormonal contraception for patients taking Incivek and Sovaldi) during treatment and for at least 6 months after treatment has concluded; and 7. Documentation that routine monthly pregnancy tests are performed during this time; 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. Prescriber is an infectious disease specialist, gastroenterologist, hepatologist, or other hepatitis specialist. 10. Documentation of a viral load taken within 6 months of beginning therapy. 11. Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved. 12. Lost or stolen medication replacement requests will not be authorized. 13. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents. <u>Incivek</u> • Patient has a documented diagnosis of hepatitis C genotype 1; and • Administered in combination with peg-interferon alfa and ribavirin. • Patient does not have HIV co-infection; and • Patient is not receiving dialysis or does not have a CrCl < 50mL/min. • HCV-RNA results are required at treatment week 4 for telaprevir (Incivek). • Additional prior authorizations will be considered with documentation of response to treatment, measured by HCV-RNA levels. • A maximum 12 weeks of therapy will be allowed for telaprevir (Incivek). <u>Victrelis</u> • Patient has a documented diagnosis of hepatitis C genotype 1; and • Administered in combination with peg-interferon alfa and ribavirin. • Patient does not have HIV co-infection; and • Patient does not have decompensated cirrhosis. • HCV-RNA results are required at treatment week 8, 12, and 24 (including lead in period) for boceprevir (Victrelis).

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Updated 1/09/2015

Sofosbuvir Containing Regimens *Use Hepatitis C Antiviral Agents PA form*	• Additional prior authorizations will be considered with documentation of response to treatment, measured by HCV-RNA levels. • Prior authorizations will be approved for a maximum of 24, 32, or 44 weeks of therapy with boceprevir (Victrelis) based on response. <u>Olysio</u> • Patient has a documented diagnosis of hepatitis C genotype 1; and • Administered in combination with peg-interferon alfa and ribavirin. • Patient does not have HIV co-infection; and • Patient does not have the NS3 Q80K polymorphism with hepatitis C genotype 1a; and • Patient is not receiving dialysis or does not have a CrCl < 30mL/min. • HCV-RNA results are required at treatment week 4 for simeprevir (Olysio). • Additional prior authorizations will be considered with documentation of response to treatment, measured by HCV-RNA levels. • A maximum 12 weeks of therapy will be allowed. <u>Sofosbuvir Containing Regimens</u> • Patient is not receiving dialysis or does not have a CrCl < 30mL/min. • Patient does not have decompensated cirrhosis; and • Documentation the patient has stage 3 or greater fibrosis as confirmed by a liver biopsy. • Treatment Regimens for Sovaldi: o Genotype 1: Patient has a documented diagnosis of hepatitis C genotype 1 (mono-infected or HCV/HIV co-infected) and used in combination with peg-interferon alfa and ribavirin. A maximum 12 weeks therapy will be allowed. o Genotype 2: Patient has a documented diagnosis of hepatitis C genotype 2 (mono-infected or HCV/HIV co-infected) and used in combination with ribavirin. A maximum 12 weeks therapy will be allowed. o Genotype 3: Patient has a documented diagnosis of hepatitis C genotype 3 (mono-infected or HCV/HIV co-infected) and used in combination with ribavirin. A maximum 24 weeks therapy will be allowed. o Genotype 4: Patient has a documented diagnosis of hepatitis C genotype 4 (mono-infected or HCV/HIV co-infected) and used in combination with peg-interferon alfa and ribavirin. A maximum 12 weeks of therapy will be allowed. o Hepatocellular carcinoma: Patient has a documented diagnosis of hepatitis C genotype 1, 2, 3, 4 with a diagnosis of hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and in combination with ribavirin for up to 48 weeks or until liver transplantation, whichever comes first. Milan criteria are defined as: ▪ One lesion smaller than 5cm in diameter for subjects with a single lesion; ▪ Up to 3 lesions smaller than 3cm in diameter in subjects with multiple lesions; ▪ No extrahepatic manifestations ▪ No vascular invasion. • Where applicable, requests for peg-interferon alfa free regimens will be considered on a case-by-case basis for patients with

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Updated 1/09/2015

	hepatitis C genotype 1 or 4 where peg-interferon alfa is contraindicated. Contraindications include: documented life-threatening side effects; decompensated hepatic disease; autoimmune hepatitis and other autoimmune disorders; a baseline neutrophil count below 90,000/µL, or a baseline hemoglobin below 10g/dL; and a history of preexisting unstable cardiac disease. • Requests for ledipasvir/sofosbuvir will only be considered for patients with a documented diagnosis of Hepatitis C, genotype 1 who meet the criteria as listed in the previous bullet for a contraindication to peg-interferon alfa and all remaining criteria.
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, 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 1/09/2015

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 6 years of age or older; and 2. Has a diagnosis of cystic fibrosis with one of the following mutations in the CFTR gener: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, and S549R as detected by a FDA-cleared CF mutation test; and 3. Prescriber is a CF specialist or pulmonologist; and 4. Patient does not have one of the following infections: *Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abcessus*.
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.

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Updated 1/09/2015

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.
Linezolid (Zyvox®) *Use Zyvox® PA form*	Prior authorization is required for Zyvox®. Payment for 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.
Long-Acting Narcotics *Use Long-Acting Narcotics PA form*	Prior authorization is required for all non-preferred long-acting narcotics. Payment will be considered under the following conditions: 1. There is documentation of previous trials and therapy failures with two (2) chemically distinct preferred long-acting narcotics (such as extended-release morphine sulfate, Opana ER and methadone) at therapeutic doses, and 2. A trial and therapy failure with fentanyl patch at maximum tolerated doses, and 3. A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization, and 4. 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. 5. Requests for long-acting narcotics will only be considered for FDA approved dosing. 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 1/09/2015

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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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, FazaClo, Invega, Metozolv ODT, Risperdal M-Tab, Suboxone Film, 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.

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. 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 1/09/2015

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. 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 1/09/2015

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 to the Quitline Iowa program for counseling. 2) Confirmation of enrollment in the Quitline Iowa counseling program is required for approval. Continuation therapy is available only with documentation of ongoing participation in the Quitline Iowa 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. Payment for oral vasopressin derivatives of posterior pituitary hormone products used in the treatment of primary nocturnal enuresis will be authorized for patients who are six years of age or older for periods of six months. Approvals will be granted for subsequent six-month periods only after a drug-free interval to assess the need for continued therapy. 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.
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. 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 1/09/2015

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.

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. 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 1/09/2015

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. 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 1/09/2015

Oral Constipation Agents	Prior authorization is required for lubiprostone (Amitiza®) and linaclotide (Linzess™). 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®) 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. 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 1/09/2015

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. Short Ragweed Pollen (Ragwitek®) In addition to the above criteria being met: • 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. Grass Pollen (Grastek®) In addition to the above criteria being met: • 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. 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 1/09/2015

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: Chronic Lung Disease (CLD) of Prematurity • 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. Prematurity (without CLD of Prematurity or Congenital Heart Disease) • Patient is less than 12 months of age at start of therapy with a gestational age of less than 29 weeks. Neuromuscular Disorders or Anatomic Pulmonary Abnormalities • 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. Hemodynamically Significant Congenital Heart Disease (CHD) • 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. Immunocompromised Children • 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. 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 1/09/2015

Pregabalin (Lyrica®) *Use Chronic Pain Syndromes PA form*	*See Chronic Pain Syndromes Prior Authorization Criteria.*
Proton Pump Inhibitors *Use Proton Pump Inhibitor PA form*	Prior authorization is not required for preferred proton pump inhibitors (PPI) for doses within the established quantity limits of one unit per day. Requests for PPIs exceeding one unit per day 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.

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Updated 1/09/2015

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. 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 1/09/2015

Rivaroxaban (Xarelto®) *Use Rivaroxaban (Xarelto®) PA form*	Prior authorization is required for rivaroxaban (Xarelto®). Payment will be considered under the following conditions: 1. Patient is 18 years of age or older; and 2. Patient does not have a mechanical prosthetic heart valve; and 3. Patient does not have active bleeding; and 4. Patient is not pregnant; and 5. Patient does not have severe renal impairment (CrCl < 15mL/min). Atrial Fibrillation • Patient has a diagnosis of non-valvular atrial fibrillation; and • Documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial); and • Presence of at least one additional risk factor for stroke, with a $CHADS_2$ score ≥ 1. • For a CrCl > 50mL/min a dose of 20mg once daily will be considered; or • For a CrCl 15 to 50mL/min a dose of 15mg once daily will be considered. Treatment and Prevention of DVT or PE • Documentation of a previous trial and therapy failure with warfarin (recurrent DVT, recurrent PE, TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial); and • Patient does not have a CrCl < 30mL/min; and • Patient does not have significant liver disease (hepatitis or cirrhosis). • For treatment of acute DVT or PE a dose of 15mg twice daily for 21 days followed by 20mg once daily for remaining treatment will be considered; or • For prevention of DVT or PE a dose of 20mg once daily will be considered. Prophylaxis of DVT following Hip or Knee Replacement • Patient does not have a CrCl < 30mL/min; and • Patient does not have significant liver disease (hepatitis or cirrhosis); and • For patients undergoing hip replacement, patient is not undergoing staged bilateral total hip replacement • Requests will be approved for the following dosing: o Hip replacement: 10mg daily for up to 35 days following hip replacement; or o Knee replacement: 10mg daily for up to 12 days following knee replacement. 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. 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 1/09/2015

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). Although intermittent therapy is recommended, quantity limits will allow for 30 tablets per 30 days supply without PA for preferred medications. 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 a previous trial and therapy failure with the preferred agent(s). Payment for non-preferred non-benzodiazepine sedative/hypnotics will be considered when there is: 1) A diagnosis of insomnia, 2) Medications with a side effect of insomnia (i.e. stimulants) are decreased in dose, changed to a short acting product, and/or discontinued, 3) Enforcement of good sleep hygiene is documented. 4) All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses. *5)* Patient has a documented trial and therapy failure with zaleplon.
Selected Brand Name Drugs *Use Selected Brand Name PA forms*	Prior authorization is required for selected brand-name drugs, as determined by the Department, for which there is available an "A" rated bioequivalent generic product as determined by the Federal Food and Drug Administration, unless the brand drug has been designated by the Department as preferred (payable) under the Iowa Medicaid Preferred Drug List (PDL). For prior authorization to be considered, the prescriber must submit a completed Selected Brand Name PA form and Iowa Medicaid MedWatch form with: 1. Documentation of trials and therapy failures with two different generic manufacturers of the same chemical entity. If an allergy to an inactive component is suspected, the second trial must be with a generic product that does not contain the allergen, if available. 2. Documentation of the failure must include the specific adverse reaction as defined by the FDA (See Section B of the MedWatch form). Intolerances, such as nausea or vomiting, to the generic drug will not be considered as a basis for approval. Trials may be overridden when evidence is provided that use of the generic product would be medically contraindicated.

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. 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 1/09/2015

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.
Short Acting Narcotics *Use Short Acting Narcotics PA form*	Prior authorization is required for all non-preferred short acting narcotics. Payment will be considered for cases in which there is documentation of previous trials and therapy failures with three (3) chemically distinct preferred short acting narcotics (based on narcotic ingredient only) at therapeutic doses, unless evidence is provided that use of these products 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 to the Quitline Iowa program for counseling. 2) Confirmation of enrollment and ongoing participation in the Quitline Iowa 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. 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 1/09/2015

Sodium Oxybate (Xyrem®) *Use Sodium Oxybate (Xyrem®) PA form*	Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered for patients 16 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® Success 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.

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. 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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Testosterone Products *Use TestosteroneProducts PA form*	Prior authorization is required for testosterone products. 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 symptoms of sexual dysfunction, erectile dysfunction and infertility will not be considered. Payment for a diagnosis of hypogonadism (testosterone deficiency) 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 at least one of the signs and symptoms specific to androgen deficiency a. Incomplete or delayed sexual development b. Breast discomfort, gynecomastia c. Loss of body hair, reduction in shaving frequency d. Very small (<5mL) or shrinking testes e. Hot flushes, sweats f. Height loss, low trauma fracture, low bone mineral density; and 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 of how the patient's specific symptoms have responded to therapy; and 3. Documentation the patient has not experienced a hematocrit > 54% or an increase in PSA > 1.4ng/mL in the past 12 months. Requests for FDA approved and compendia indications other than hypogonadism will not be subject to prior authorization criteria with adequate documentation of the diagnosis. 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. 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 1/09/2015

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 with decompensated liver disease with a Child-Pugh score > 6 (Class B & C). 3. Patients with a history of ascites. 4. Patients with hepatic encephalopathy. 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.
Topical Retinoids for Acne *Use Topical Retinoids for Acne PA form*	Prior authorization is required for all prescription topical retinoid products. Payment for prescription topical retinoid products will be considered under the following conditions: 1. Previous trial and therapy failure with a preferred over-the-counter benzoyl peroxide product, and 2. Previous trials and therapy failures with two preferred topical and/or oral antibiotics for the treatment of mild to moderate acne (non-inflammatory and inflammatory), and drug-induced acne. 3. Payment for non-preferred topical retinoid products will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. 4. Trials and therapy failure will not be required for those patients presenting with a preponderance of comedonal acne. 5. Skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive automatic approval for lifetime use of topical retinoid products. 6. Requests for non-preferred combination products may only be considered after documentation of separate trials and therapy failures with the individual ingredients. 7. Trial and therapy failure with a preferred topical antipsoriatic agent will not be required for Tazorac for a psoriasis diagnosis. 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. 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 1/09/2015

Trametinib (Mekinist™) *Use Trametinib (Mekinist™) PA form*	Prior authorization is required for trametinib (Mekinist™). 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 documented diagnosis of unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutation as detected but an FDA-approved test; and 3. Patient has not received prior therapy with a BRAF-inhibitor; and 4. Prescriber is an oncologist. If the criteria for coverage are met, authorizations will be given at three (3) month intervals. Updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued.
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.)
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.