

## 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. 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.

Updated 5/1/2013

<p><b>ADD/ADHD/ NARCOLEPSY AGENTS</b></p> <p><i>Use ADD/ADHD/Narcolepsy Agents PA form</i></p>	<p>Prior authorization (PA) is required for ADD/ADHD/Narcolepsy agents for patients 21 years of age or older under the following conditions:</p> <ol style="list-style-type: none"> <li>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).</li> <li>2. Narcolepsy with diagnosis confirmed with a recent sleep study (ESS, MSLT, PSG).</li> <li>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.</li> </ol> <p>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.</p> <p>The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.</p>
<p><b>Alpha<sub>2</sub> Agonists, Extended-Release</b></p> <p><i>Intuniv™ Kapvay™</i></p> <p><i>Use Alpha<sub>2</sub> Agonists, Extended-Release PA form</i></p>	<p>Prior authorization is required for extended-release alpha<sub>2</sub> agonists. Payment will be considered for patients when the following is met:</p> <ol style="list-style-type: none"> <li>1. The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and</li> <li>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</li> <li>3. Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant; and</li> <li>4. Previous trial and therapy failure at a therapeutic dose with atomoxetine (Strattera®).</li> </ol> <p>The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.</p>
<p><b>Alpha<sub>1</sub>-Proteinase Inhibitor Enzymes</b></p> <p><i>Use Miscellaneous PA form</i></p>	<p>Prior authorization is required for Alpha<sub>1</sub>-Proteinase Inhibitor enzymes. Payment will be authorized only for cases in which there is a diagnosis of congenital alpha<sub>1</sub>-proteinase inhibitor (alpha<sub>1</sub>-PI; alpha1-antitrypsin) deficiency with clinically demonstrable panacinar emphysema. Payment for a non-preferred Alpha<sub>1</sub>-Proteinase Inhibitor enzyme will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent.</p>
<p><b>Amylino Mimetic (Symlin®)</b></p> <p><i>Use Amylino Mimetic (Symlin®) form</i></p>	<p>Prior authorization is required for amylin 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 HbA1C despite multiple titration with basal/bolus insulin dosing regimens. 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 HbA1C since the beginning of the initial prior authorization period.</p>

**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.**

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Updated 5/1/2013

<p><b>Angiotensin Receptor Blocker Before ACE Inhibitor</b></p> <p><i>Use Angiotensin Receptor Blocker Before ACE Inhibitor PA form</i></p>	<p>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.</p>
<p><b>Anti-Acne</b></p> <p><i>Use Anti-Acne PA form</i></p>	<p>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:</p> <ol style="list-style-type: none"> <li>1. Previous trial and therapy failure with a preferred over-the-counter benzoyl peroxide product, which is covered by the program without prior authorization.</li> <li>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.</li> <li>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).</li> <li>4. Requests for non-preferred combination products may only be considered after documented separate trials and therapy failures with the individual ingredients.</li> </ol> <p>The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.</p>

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Updated 5/1/2013

<p><b>Antiemetic-5HT3 Receptor Antagonists/ Substance P Neurokinin Agents</b></p> <p><i>Use Antiemetic-5HT3 Receptor Antagonists/ Substance P Neurokinin Agents form</i></p>	<p>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.</p> <p>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.</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <p>Aprepitant (N)/Emend® (N):</p> <ul style="list-style-type: none"> <li>4 – 125mg capsules</li> <li>8 – 80mg capsules</li> </ul> <p>Dolasetron (N)/Anzemet® (N):</p> <ul style="list-style-type: none"> <li>5 – 50mg/100mg tablets</li> <li>4 vials (100mg/5mL)</li> <li>8 ampules (12.5mg/0.625mL)</li> </ul> <p>Granisetron (N)/Kytril®/Granisol™ (N):</p> <ul style="list-style-type: none"> <li>8 – 1mg tablets</li> <li>30mL – oral solution (1mg/5mL)</li> <li>8 vials (1mg/mL)</li> <li>2 vials (4mg/mL)</li> </ul> </td> <td style="width: 50%; vertical-align: top;"> <p>Ondansetron (P)/Zofran® (N):</p> <ul style="list-style-type: none"> <li>12 – 4mg tablets</li> <li>12 – 8mg tablets</li> <li>4 – 24mg tablets</li> <li>4 – 20mL vials (2mg/mL)</li> <li>8 – 2mL vials (2mg/mL)</li> </ul> <p>Ondansetron ODT (P)/Zofran® ODT (N):</p> <ul style="list-style-type: none"> <li>12 – 4mg tablets</li> <li>12 – 8mg tablets</li> </ul> <p>Ondansetron Oral Solution (N)/ Zofran® Oral Solution (N)</p> <ul style="list-style-type: none"> <li>50mL/month – oral solution (4mg/5mL)</li> </ul> <p>Palonosetron (N)/ Aloxi® (N):</p> <ul style="list-style-type: none"> <li>4 vials (0.25mg/5mL)</li> </ul> </td> </tr> </table>	<p>Aprepitant (N)/Emend® (N):</p> <ul style="list-style-type: none"> <li>4 – 125mg capsules</li> <li>8 – 80mg capsules</li> </ul> <p>Dolasetron (N)/Anzemet® (N):</p> <ul style="list-style-type: none"> <li>5 – 50mg/100mg tablets</li> <li>4 vials (100mg/5mL)</li> <li>8 ampules (12.5mg/0.625mL)</li> </ul> <p>Granisetron (N)/Kytril®/Granisol™ (N):</p> <ul style="list-style-type: none"> <li>8 – 1mg tablets</li> <li>30mL – oral solution (1mg/5mL)</li> <li>8 vials (1mg/mL)</li> <li>2 vials (4mg/mL)</li> </ul>	<p>Ondansetron (P)/Zofran® (N):</p> <ul style="list-style-type: none"> <li>12 – 4mg tablets</li> <li>12 – 8mg tablets</li> <li>4 – 24mg tablets</li> <li>4 – 20mL vials (2mg/mL)</li> <li>8 – 2mL vials (2mg/mL)</li> </ul> <p>Ondansetron ODT (P)/Zofran® ODT (N):</p> <ul style="list-style-type: none"> <li>12 – 4mg tablets</li> <li>12 – 8mg tablets</li> </ul> <p>Ondansetron Oral Solution (N)/ Zofran® Oral Solution (N)</p> <ul style="list-style-type: none"> <li>50mL/month – oral solution (4mg/5mL)</li> </ul> <p>Palonosetron (N)/ Aloxi® (N):</p> <ul style="list-style-type: none"> <li>4 vials (0.25mg/5mL)</li> </ul>
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<p><b>Anti-Fungal</b></p> <p><i>Use Anti-Fungal PA form</i></p>	<p>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.</p>		

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Updated 5/1/2013

<p><b>Antihistamines</b></p> <p><i>Use Antihistamine PA form</i></p>	<p>Prior authorization is required for all non-preferred oral antihistamines.</p> <p>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.</p> <p>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.</p> <p>The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.</p>
<p><b>Anti-Thrombotics, Injectable</b></p> <p><i>Use Anti-Thrombotic Injectable PA form</i></p>	<p>Prior authorization is required for use of any preferred injectable anti-thrombotic agent longer than 10 consecutive days. Prior authorization will be required for all non-preferred injectable anti-thrombotic agents beginning the first day of therapy. Payment for non-preferred anti-thrombotic injectable agents will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. Payment for usage of injectable anti-thrombotic agents beyond this limit will be authorized for cases in which there is a clinical diagnosis of:</p> <ol style="list-style-type: none"> <li>1. Pregnancy or planned pregnancy</li> <li>2. Cancer-associated thromboembolic disease</li> <li>3. Anti-thrombin III deficiency</li> <li>4. Warfarin allergy</li> <li>5. History of thrombotic event while on therapeutic anticoagulant therapy.</li> <li>6. Total hip arthroplasty.</li> </ol>
<p><b>Becaplermin (Regranex®)</b></p> <p><i>Use Regranex® PA form</i></p>	<p>Prior authorization is required for Regranex®. Payment for new prescriptions will be authorized for ten weeks for patients who meet the following criteria:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond</li> <li>2. Inadequate response to 2 weeks of wound debridement and topical moist wound dressing</li> </ol> <p>Longer than 10 weeks will be authorized for patients who meet the following criteria: Wound has decreased in size by 30% after 10 weeks</p>

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<p><b>Biologicals for Arthritis</b>  <i>Abatacept (Orencia®)</i>  <i>Adalimumab (Humira®)</i>  <i>Anakinra (Kineret®)</i>  <i>Certolizumab Pegol (Cimzia®)</i>  <i>Etanercept (Enbrel®)</i>  <i>Infliximab (Remicade®)</i>  <i>Golimumab (Simponi™)</i></p> <p><i>Use Biologicals for Arthritis PA form</i></p>	<p>Prior authorization is required for biologicals used for arthritis. Patients initiating therapy with a biological agent must:</p> <ol style="list-style-type: none"> <li>1. Be screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage;</li> <li>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;</li> <li>3. Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and</li> <li>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.</li> </ol> <p>Payment will be considered under the following conditions:</p> <p>A diagnosis of rheumatoid arthritis (RA):</p> <ol style="list-style-type: none"> <li>1. 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 (hydroxychloroquine, sulfasalazine, leflunomide, or minocycline).</li> <li>2. 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.</li> </ol> <p>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).</p> <p>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).</p> <p>The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated</p> <p>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.</p>
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<p><b>Biologicals for Inflammatory Bowel Disease</b></p> <p><i>Adalimumab (Humira®)</i> <i>Certolizumab Pegol (Cimzia®)</i> <i>Infliximab (Remicade®)</i></p> <p><i>Use Biologicals for Inflammatory Bowel Disease PA form</i></p>	<p>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.</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Ulcerative colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine.</li> </ul>
<p><b>Biologicals for Plaque Psoriasis</b></p> <p><i>Alefacept (Amevive®)</i> <i>Adalimumab (Humira®)</i> <i>Etanercept (Enbrel®)</i> <i>Infliximab (Remicade®)</i></p> <p><i>Use Biologicals for Plaque Psoriasis PA form</i></p>	<p>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.</p>
<p><b>Buprenorphine (Butrans™) Transdermal System</b></p> <p><i>Use Buprenorphine (Butrans™) Transdermal System PA form</i></p>	<p>Prior authorization is required for Butrans™. Payment will be considered when the following conditions are met:</p> <ol style="list-style-type: none"> <li>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.</li> <li>2. A trial and therapy failure with fentanyl patch at maximum tolerated dose.</li> </ol> <p>The required trials may be overridden when documented evidence it provided that use of these agents would be medically contraindicated.</p>

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<p><b>Colchicine (Colcrys®)</b></p> <p><i>Use Colchicine (Colcrys®) PA form</i></p>	<p>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:</p> <ol style="list-style-type: none"> <li>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.</li> <li>2. Familial Mediterranean fever. A maximum quantity of 120 tablets per thirty (30) days will be applied for this diagnosis.</li> </ol> <p>The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.</p>
<p><b>Concurrent IM/PO Antipsychotic Use</b></p> <p><i>Use Concurrent IM/PO Antipsychotic Utilization PA form</i></p>	<p>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.</p>
<p><b>Crizotinib (Xalkori®)</b></p> <p><i>Use Xalkori® PA form</i></p>	<p>Prior authorization is required for Xalkori® (crizotinib). Payment will be considered for patients when the following is met:</p> <ol style="list-style-type: none"> <li>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</li> <li>2. Is prescribed by an oncologist.</li> </ol>
<p><b>DPP-4 Inhibitors</b></p> <p><i>Use DPP-4 Inhibitor PA form</i></p>	<p>Prior authorization is required for dipeptidyl peptidase-4 (DPP-4) inhibitors and DPP-4 Inhibitor Combinations. Payment will be considered under the following conditions:</p> <ol style="list-style-type: none"> <li>1. A diagnosis of Type 2 Diabetes Mellitus</li> <li>2. Patient is 18 years of age or older</li> <li>3. The patient has not achieved HbgA1C goals using a combination of two or more antidiabetic medications (metformin, sulfonylurea, thiazolidinedione, or insulin) at maximum tolerated doses unless otherwise contraindicated.</li> </ol> <p>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. 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.</p>

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<p><b>Dalfampridine (Ampyra™)</b></p> <p><i>Use Dalfampridine (Ampyra™) PA form</i></p>	<p>Prior authorization is required for dalfampridine (Ampyra™). Payment will be considered under the following conditions:</p> <ol style="list-style-type: none"> <li>1. For patients that have a gait disorder associated with MS.</li> <li>2. Initial authorizations will be approved for 12 weeks with a baseline Timed 25-foot Walk (T25FW) assessment.</li> <li>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.</li> </ol> <p>Prior authorizations will not be considered for patients with a seizure diagnosis or in patients will moderate to severe renal impairment.</p>
<p><b>Dextromethorphan and Quinidine (Nuedexta™)</b></p> <p><i>Use Dextromethorphan and Quinidine (Nuedexta™) PA form</i></p>	<p>Prior authorization is required for Nuedexta™. Payment will be considered under the following conditions:</p> <ol style="list-style-type: none"> <li>1. Patients must have a diagnosis of pseudobulbar affect (PBA) secondary to amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS).</li> <li>2. A trial and therapy failure at a therapeutic dose with amitriptyline or an SSRI.</li> <li>3. Initial authorizations will be approved for 12 weeks with a baseline Center for Neurologic Studies Lability Scale (CNS-LS) questionnaire.</li> <li>4. Subsequent prior authorizations will be considered at 6 month intervals with documented efficacy as seen in an improvement in the CNS-LS questionnaire.</li> </ol>
<p><b>Digestive Enzymes</b></p> <p><i>Use Miscellaneous PA form</i></p>	<p>Prior authorization is required for all digestive enzymes. Payment for preferred digestive enzymes will be authorized only for cases in which there is a clinical diagnosis of malabsorption due to pancreatic insufficiency. Payment for non-preferred digestive enzymes will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred products.</p>
<p><b>Dornase Alfa (Pulmozyme®)</b></p> <p><i>Use Miscellaneous PA form</i></p>	<p>Prior authorization is required for Pulmozyme®. Payment will be authorized only for cases in which there is a diagnosis of cystic fibrosis.</p>
<p><b>Duloxetine (Cymbalta®)</b></p> <p><i>Use Chronic Pain Syndromes PA form</i></p>	<p><i>See Chronic Pain Syndromes Prior Authorization Criteria.</i></p>
<p><b>Eplerenone (Inspra®)</b></p> <p><i>Use Miscellaneous PA form</i></p>	<p>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.</p>

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.

## 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. 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.

Updated 5/1/2013

<p><b>Erythropoiesis Stimulating Agents</b></p> <p><i>Use Erythropoiesis Stimulating Agent PA form</i></p>	<p>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:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>3. For HIV-infected patients, the endogenous serum erythropoietin level must be less than or equal to 500 mU/ml to initiate therapy.</li> <li>4. No evidence of untreated GI bleeding, hemolysis, or Vitamin B-12, iron or folate deficiency.</li> </ol>
<p><b>Extended Release Formulations</b></p> <p><i>Use Extended Release Formulations PA form</i></p>	<p>Payment for a non-preferred extended release formulation will be considered when the following criteria are met:</p> <ol style="list-style-type: none"> <li>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</li> <li>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.</li> </ol> <p>The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.</p> <p>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.</p>
<p><b>Febuxostat (Uloric®)</b></p> <p><i>Use Febuxostat (Uloric®) PA form</i></p>	<p>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.</p>
<p><b>Fentanyl, Short Acting Oral Products</b></p> <p><i>Use Short Acting Oral Fentanyl Products PA form</i></p>	<p>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 <b>Black Box Warning</b>. Actiq®, Fentora®, &amp; Onsolis™:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>

**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.**

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## 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. 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.

Updated 5/1/2013

<p><b>Fifteen Day Initial Prescription Supply Limit</b></p> <p><i>Use Fifteen Day Initial Prescription Supply Limit PA form</i></p>	<p>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 <a href="http://www.iowamedicaidpdl.com">www.iowamedicaidpdl.com</a> 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.</p>
<p><b>Fingolimod (Gilenya™)</b></p>	<p>Prior authorization is required for fingolimod (Gilenya™). Payment will be considered under the following conditions:</p> <ol style="list-style-type: none"> <li>1. A diagnosis of relapsing forms of multiple sclerosis, and</li> <li>2. A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.</li> </ol> <p>The required trial may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.</p>
<p><b>Granulocyte Colony Stimulating Factor Agents</b></p> <p><i>Use Granulocyte Colony Stimulating Factor PA form</i></p>	<p>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:</p> <ol style="list-style-type: none"> <li>1. Prevention or treatment of febrile neutropenia in patients with malignancies who are receiving myelosuppressive anticancer therapy.</li> <li>2. Treatment of neutropenia in patients with malignancies undergoing myeloablative chemotherapy followed by bone marrow transplant.</li> <li>3. Mobilization of progenitor cells into the peripheral blood stream for leukapheresis collection to be used after myeloablative chemotherapy.</li> <li>4. Treatment of congenital, cyclic, or idiopathic neutropenia in symptomatic patients.</li> </ol>

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.



## 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. 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.

Updated 5/1/2013

<p><b>Incretin Mimetic</b></p> <p><i>Byetta<sup>®</sup></i> <i>Victoza<sup>®</sup></i></p> <p><i>Use Incretin Mimetic form</i></p>	<p>Prior authorization is required for incretin mimetics (Byetta<sup>®</sup> &amp; Victoza<sup>®</sup>). Payment will be considered under the following conditions: 1) Diagnosis of Type 2 diabetes mellitus, 2) Unless otherwise contraindicated, the member has not achieved HbgA1C goals using a combination of two or more antidiabetic medications (metformin, sulfonylurea, or thiazolidinedione) at maximum therapeutic doses. 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.</p>
<p><b>Insulin, Pre-Filled Pens</b></p> <p><i>Use Pre-filled Insulin Pen PA form</i></p>	<p>Prior authorization is required for pre-filled insulin pens. Prior authorization is granted when documentation indicates:</p> <ul style="list-style-type: none"> <li>• The patient’s visual or motor skills are impaired to such that they cannot accurately draw up their own insulin, and</li> <li>• There is no caregiver available to provide assistance.</li> </ul> <p>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.</p>
<p><b>Isotretinoin (Oral)</b></p> <p><i>Use Oral Isotretinoin PA form</i></p>	<p>Prior authorization is required for oral isotretinoin therapy. Payment will be approved for preferred oral isotretinoin products for acne under the following conditions:</p> <ol style="list-style-type: none"> <li>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.</li> <li>2. Patients and providers must be registered in, and meet all requirements of, the iPLEDGE (<a href="http://www.ipledgeprogram.com">www.ipledgeprogram.com</a>) risk management program.</li> </ol> <p>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</p>
<p><b>Ivacaftor (Kalydeco<sup>™</sup>)</b></p> <p><i>Use Kalydeco<sup>™</sup> PA form</i></p>	<p>Prior authorization is required for Kalydeco<sup>™</sup> (ivacaftor). Payment will be considered for patients when the following criteria are met:</p> <ol style="list-style-type: none"> <li>1. Patient is 6 years of age or older; and</li> <li>2. Has a diagnosis of cystic fibrosis with a G551D mutation in the CFTR gene as detected by a FDA-cleared CF mutation test; and</li> <li>3. Prescriber is a CF specialist or pulmonologist; and</li> <li>4. Patient does not have one of the following infections: <i>Burkholderia cenocepacia, dolosa, or Mycobacterium abscessus</i>.</li> </ol>

## 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. 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.

Updated 5/1/2013

<p><b>Ketorolac</b></p> <p><i>Use Ketorolac PA form</i></p>	<p>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 <b>Black Box Warning</b>. 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:</p> <ol style="list-style-type: none"> <li>1. For oral therapy, documentation of recent IM/IV ketorolac tromethamine injection including administration date and time, and the total number of injections given.</li> <li>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.</li> <li>3. Diagnosis indicating moderately severe, acute pain.</li> </ol> <p>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.</p>
<p><b>Lidocaine Patch (Lidoderm®)</b></p> <p><i>Use Lidocaine Patch (Lidoderm®) PA form</i></p>	<p>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.</p>
<p><b>Linezolid (Zyvox®)</b></p> <p><i>Use Zyvox® PA form</i></p>	<p>Prior authorization is required for Zyvox®. Payment for Zyvox® will be authorized when there is documentation that:</p> <ol style="list-style-type: none"> <li>1. Prescriber is an infectious disease (ID) physician or has consulted ID physician (Telephone consultation is acceptable).</li> <li>2. Patient has an active infection and meets one of the following diagnostic criteria: <ul style="list-style-type: none"> <li>• Vancomycin-resistant Enterococcus (VRE) and no alternative regimens with documented efficacy are available and VRE is not in lower urinary tract**.</li> <li>• Methicillin-resistant Staph aureus (MRSA) and patient is intolerant to vancomycin*</li> <li>• Methicillin-resistant Staph epidermis (MRSE) and patient is intolerant to vancomycin*</li> </ul> </li> </ol> <p>*Severe intolerance to vancomycin is defined as:</p> <ul style="list-style-type: none"> <li>– Severe rash, immune-complex mediated, determined to be directly related to vancomycin administration</li> <li>– Red-man’s syndrome (histamine-mediated), refractory to traditional counter measures (e.g., prolonged IV infusion, premedicated with diphenhydramine)</li> </ul> <p>**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.</p>

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. 16

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## 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. 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.

Updated 5/1/2013

<p><b>Mifepristone (Korlym®)</b></p> <p><i>Use Mifepristone (Korlym) PA form</i></p>	<p>Prior authorization is required for mifepristone (Korlym®). Payment will be considered for patients when the following is met:</p> <ol style="list-style-type: none"> <li>1. The patient is 18 years of age or older: and</li> <li>2. Has a diagnosis of endogenous Cushing's Syndrome with hyperglycemia secondary to hypercortisolism in patients with Type 2 Diabetes or glucose intolerance: and</li> <li>3. Patient must have failed surgery or is not a candidate for surgery: and</li> <li>4. Prescriber is an endocrinologist: and</li> <li>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.</li> </ol>
<p><b>Milnacipran (Savella™)</b></p> <p><i>Use Chronic Pain Syndromes PA form</i></p>	<p><i>See Chronic Pain Syndromes Prior Authorization Criteria.</i></p>
<p><b>Modified Formulations</b></p> <p><i>Use Modified Formulations PA form</i></p>	<p>Payment for a non-preferred isomer, prodrug, or metabolite will be considered when the following criteria are met:</p> <ol style="list-style-type: none"> <li>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</li> <li>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.</li> </ol> <p>The required trials may be overridden when documented evidence is provided that use of these preferred agent(s) would be medically contraindicated.</p> <p>Prior authorization is required for the following modified dosage forms: Abilify Discmelt, Aplenzin, Aricept ODT, FazaClo, Invega, Metozolv ODT, Pristiq, Risperdal M-Tab, Suboxone Film, Trilipix, Xopenex, Zyprexa Zydis.</p>
<p><b>Muscle Relaxants</b></p> <p><i>Use Muscle Relaxant PA form</i></p>	<p>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.</p>

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.

## 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. 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.

Updated 5/1/2013

<p><b>Narcotic Agonist-Antagonist Nasal Sprays</b></p> <p><i>Use Narcotic Agonist/Antagonist Nasal Spray PA form</i></p>	<p>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.</p> <p>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.</p> <p>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.</p>
<p><b>Nebivolol (Bystolic®)</b></p> <p><i>Use Nebivolol (Bystolic®) PA form</i></p>	<p>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.</p>
<p><b>Nicotine Replacement Therapy</b></p> <p><i>Use Nicotine Replacement Therapy PA form</i></p>	<p>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:</p> <ol style="list-style-type: none"> <li>1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.</li> <li>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.</li> <li>3) Approvals will only be granted for patients eighteen years of age and older.</li> <li>4) The maximum allowed duration of therapy is twelve weeks total combined therapy within a twelve-month period.</li> <li>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.</li> <li>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.</li> <li>7) The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation.</li> </ol>

**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.**

## 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. 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.

Updated 5/1/2013

<p><b>Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products</b></p> <p><i>Use Non-Parenteral Vasopressin Deriv. of Posterior Pituitary Hormone Products PA form</i></p>	<p>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:</p> <ol style="list-style-type: none"> <li>1. Diabetes Insipidus.</li> <li>2. Hemophilia A.</li> <li>3. Von Willebrand's disease.</li> </ol> <p>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.</p>
<p><b>Non-Preferred Drug</b></p> <p><i>Use Non-Preferred Drug PA form</i></p>	<p>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.</p>
<p><b>Nonsteroidal Anti-inflammatory Drugs</b></p> <p><i>Use Non-Steroidal Anti-inflammatory Drug PA form</i></p>	<p>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 inhibitors.</p> <ol style="list-style-type: none"> <li>1. Requests for a non-preferred nsaid must document previous trials and therapy failures with at least three preferred nsaids.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ol> <p>The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.</p>

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.

## 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. 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.

Updated 5/1/2013

<p><b>Omalizumab (Xolair®)</b></p> <p><i>Use Xolair® PA form</i></p>	<p>Prior authorization is required for Xolair®. Payment for Xolair® will be authorized when the following criteria are met:</p> <ol style="list-style-type: none"> <li>1. Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and</li> <li>2. Patient is 12 years of age or older; and</li> <li>3. Pretreatment IgE level is between 30 IU/mL and 700 IU/mL; and</li> <li>4. Patient's weight is between 30 kg and 150 kg; and</li> <li>5. History of positive skin or RAST test to a perennial aeroallergen; and</li> <li>6. Prescriber is an allergist, immunologist, or pulmonologist; and</li> <li>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.</li> <li>8. Patient must have access to an EpiPen to treat allergic reactions that may occur after administration of Xolair®.</li> </ol> <p>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.</p> <p>The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.</p>
<p><b>Oxycodone CR/ER (OxyContin®)</b></p> <p><i>Use OxyContin® PA form</i></p>	<p>Extended release oxycodone/OxyContin® is non-preferred except for patients being treated for cancer related pain. Prior authorization at any dose twice daily for cancer related pain will be approved. For all other diagnoses, payment will be considered under the following conditions:</p> <ol style="list-style-type: none"> <li>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</li> <li>2. A trial and therapy failure with fentanyl patch at maximum tolerated doses, and</li> <li>3. A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization, and</li> <li>4. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <a href="https://pmp.iowa.gov/IAPMPWebCenter/">https://pmp.iowa.gov/IAPMPWebCenter/</a> prior to requesting prior authorization.</li> <li>5. Requests will only be considered for 12 hour dosing.</li> </ol> <p>The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.</p>

## 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. 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.

Updated 5/1/2013

<p><b>Palivizumab (Synagis®)</b></p> <p><i>Use Palivizumab PA form</i></p>	<p><u>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 <a href="http://www.cdc.gov/surveillance/nrevss/rsv/reports.html">http://www.cdc.gov/surveillance/nrevss/rsv/reports.html</a>.</u></p> <ul style="list-style-type: none"> <li>• <u>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.</u></li> <li>• <u>Medicaid will provide coverage of prescription drugs that protect against RSV consistent with the American Academy of Pediatrics (AAP) Guidelines for Infants and Children at Risk for Severe Illness due to RSV Infection.</u></li> <li>• <u>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.</u></li> </ul> <p>Prior authorization is required for therapy with palivizumab. Prior authorizations will be approved for a maximum of five doses per patient. No allowances will be made for a sixth dose. Some patients may receive a maximum of three doses, dependent on gestational and chronological age at the start of the RSV season. Payment for palivizumab will be considered for patients who meet one of the following criteria:</p> <p><u>Chronic Lung Disease (CLD)</u></p> <ul style="list-style-type: none"> <li>• Patient is less than 24 months of age at start of therapy and has chronic lung disease of prematurity (i.e. bronchopulmonary dysplasia) requiring medication (bronchodilator, corticosteroid, or diuretic therapy) or oxygen within six months before the anticipated start of RSV season.</li> </ul> <p><u>Prematurity</u></p> <ul style="list-style-type: none"> <li>• Patient is less than 12 months of age at start of therapy with a gestational age of less than 29 weeks.</li> <li>• Patient is less than 6 months of age at start of therapy with a gestational age of 29 weeks through 31 weeks.</li> <li>• Patient is less than 3 months of age at start of therapy or born during the RSV season with a gestational age of 32 weeks through 34 weeks and has one of two risk factors. Risk factors include: day care attendance or siblings less than 5 years of age in household. Doses will be limited to a maximum of 3 doses or until patient reaches 90 days of age, which ever comes first.</li> </ul> <p><u>Severe Neuromuscular Disease or Congenital Abnormalities</u></p> <ul style="list-style-type: none"> <li>• Patient is 12 months of age or younger at the start of therapy and has either severe neuromuscular disease or congenital abnormalities of the airway that compromises handling of respiratory secretions.</li> </ul> <p><u>Congenital Heart Disease (CHD)</u></p> <ul style="list-style-type: none"> <li>• Patient is less than 24 months of age at start of therapy and has hemodynamically significant congenital heart disease further defined by any of the following: Receiving medication to control congestive heart failure, moderate to severe pulmonary hypertension, or cyanotic congenital heart disease.</li> </ul> <p><u>Severe Immunodeficiency</u></p> <ul style="list-style-type: none"> <li>• Patient is less than 24 months of age at start of therapy and has severe immunodeficiencies (e.g., severe combined immunodeficiency or advanced acquired immunodeficiency syndrome).</li> </ul>
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**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.**



## 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. 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.

Updated 5/1/2013

<p><b>Roflumilast (Daliresp™)</b></p> <p><i>Use Roflumilast (Daliresp™) PA form</i></p>	<p>Prior authorization is required for roflumilast (Daliresp™). Payment will be considered for patients 18 years of age or older when the following is met:</p> <ol style="list-style-type: none"> <li>1. A diagnosis of severe COPD with chronic bronchitis as documented by spirometry results, and</li> <li>2. A smoking history of ≥ 20 pack-years, and</li> <li>3. Currently on a long-acting bronchodilator in combination with an inhaled corticosteroid with documentation of inadequate control of symptoms, and</li> <li>4. A history of at least one exacerbation in the past year requiring treatment with oral glucocorticosteroids.</li> </ol> <p>The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.</p>
<p><b>Sedative/Hypnotics- Non-Benzodiazepine</b></p> <p><i>Use Sedative/Hypnotics- Non-Benzodiazepine PA form</i></p>	<p>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.</p> <p>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:</p> <ol style="list-style-type: none"> <li>1) A diagnosis of insomnia,</li> <li>2) Medications with a side effect of insomnia (i.e. stimulants) are decreased in dose, changed to a short acting product, and/or discontinued,</li> <li>3) Enforcement of good sleep hygiene is documented.</li> <li>4) All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses.</li> <li>5) Patient has a documented trial and therapy failure with zaleplon.</li> </ol>
<p><b>Selected Brand Name Drugs</b></p> <p><i>Use Selected Brand Name PA forms</i></p>	<p>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:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> </ol> <p>Trials may be overridden when evidence is provided that use of the generic product would be medically contraindicated.</p>

**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.**

## 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. 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.

Updated 5/1/2013

<p><b>Serotonin 5-HT1-receptor Agonists</b></p> <p><i>Use Serotonin 5-HT1-receptor Agonists PA form</i></p>	<p>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:</p> <ol style="list-style-type: none"> <li>1. The diagnosis requiring therapy.</li> <li>2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.</li> </ol>
<p><b>Short Acting Narcotics</b></p> <p><i>Use Short Acting Narcotics PA form</i></p>	<p>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.</p>
<p><b>Smoking Cessation Therapy-Oral</b></p> <p><i>Chantix® Bupropion SR</i></p> <p><i>Use Smoking Cessation Therapy-Oral PA form</i></p>	<p>Prior Authorization is required for varenicline (Chantix<sup>®</sup>) or bupropion SR that is FDA approved for smoking cessation. Requests for authorization must include:</p> <ol style="list-style-type: none"> <li>1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.</li> <li>2) Confirmation of enrollment and ongoing participation in the Quitline Iowa counseling program is required for approval and continued coverage.</li> <li>3) Approvals will only be granted for patients eighteen years of age and older.</li> <li>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.</li> <li>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.</li> <li>6) The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation</li> </ol>



## 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. 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.

Updated 5/1/2013

<p><b>Sodium Oxybate (Xyrem®)</b></p> <p><i>Use Sodium Oxybate (Xyrem®) PA form</i></p>	<p>Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered for patients 16 years of age or older under the following conditions:</p> <ol style="list-style-type: none"> <li>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.</li> <li>2. A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant.</li> <li>3. Requests for patients with a prior history of substance abuse, concurrent use with a sedative hypnotic, or a semialdehyde dehydrogenase deficiency will not be considered.</li> </ol> <p>The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.</p>
<p><b>Step Therapy Edits</b></p> <p><i>Use Non-Preferred Drug PA form</i></p>	<p>Designated therapeutic drug classes are subject to step therapy edits. These therapeutic classes, as well as the step edit requirements, are identified on the Iowa Medicaid Preferred Drug List posted on the website <a href="http://www.iowamedicaidpdl.com">www.iowamedicaidpdl.com</a> under the Preferred Drug Lists tab. Providers should submit a Prior Authorization request for override consideration.</p> <p>Therapeutic Classes Included: Antipsychotics-Atypicals</p>
<p><b>Thrombopoietin Receptor Agonists</b></p> <p><i>Use Thrombopoietin Receptor Agonists PA form</i></p>	<p>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 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.</p>

## 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. 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.

Updated 5/1/2013

<p><b>Topical Retinoids for Acne</b></p> <p><i>Use Topical Retinoids for Acne PA form</i></p>	<p>Prior authorization is required for all prescription topical retinoid products. Payment for prescription topical retinoid products will be considered under the following conditions:</p> <ol style="list-style-type: none"> <li>1. Previous trial and therapy failure with a preferred over-the-counter benzoyl peroxide product, and</li> <li>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.</li> <li>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.</li> <li>4. Trials and therapy failure will not be required for those patients presenting with a preponderance of comedonal acne.</li> <li>5. Skin cancer, lamellar ichthyosis, and Darier’s disease diagnoses will receive automatic approval for lifetime use of topical retinoid products.</li> <li>6. Requests for non-preferred combination products may only be considered after documentation of separate trials and therapy failures with the individual ingredients.</li> <li>7. Trial and therapy failure with a preferred topical antipsoriatic agent will not be required for Tazorac for a psoriasis diagnosis.</li> </ol> <p>The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.</p>
<p><b>Vemurafenib (Zelboraf™)</b></p> <p><i>Use Zelboraf™ (vemurafenib) PA form</i></p>	<p>Prior authorization is required for Zelboraf™. Payment will be considered for patients when the following criteria are met:</p> <ol style="list-style-type: none"> <li>1. Patient is 18 years of age or older; and</li> <li>2. Has a diagnosis of unresectable or metastatic melanoma with BRAF<sup>V600E</sup> mutation as detected by an FDA-approved test; and</li> <li>3. Prescriber is an oncologist.</li> </ol> <p>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.</p>
<p><b>Vilazodone (Viibryd™)</b></p> <p><i>Use Vilazodone (Viibryd™) PA form</i></p>	<p>Prior authorization is required for Viibryd™. Requests for doses above the manufacturer recommended dose will not be considered. Payment will be considered for patients when the following criteria are met:</p> <ol style="list-style-type: none"> <li>1. The patient has a diagnosis of Major Depressive Disorder (MDD) and is 18 years of age or older; and</li> <li>2. Documentation of a previous trial and therapy failure at a therapeutic dose with one preferred generic SSRI; and</li> <li>3. Documentation of a previous trial and therapy failure at a therapeutic dose with one preferred generic SNRI; and</li> <li>4. Documentation of a previous trial and therapy failure at a therapeutic dose with an additional generic antidepressant from any class.</li> </ol> <p>The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.</p>

**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.** 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.

**Updated 5/1/2013**

<p><b>Vitamins, Minerals and Multiple Vitamins</b></p> <p><i>Use Vitamin/Mineral PA form</i></p>	<p>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.)</p>
<p><b>Vusion™ Ointment</b></p> <p><i>Use Vusion™ Ointment PA form</i></p>	<p>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.</p>