



Iowa Department of Human Services

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INFORMATIONAL LETTER NO.1891-MC-FFS

DATE: February 20, 2018

TO: Iowa Medicaid Physicians, Dentists, Advanced Registered Nurse Practitioners, Therapeutically Certified Optometrists, Podiatrists, Pharmacies, Home Health Agencies, Rural Health Clinics, Clinics, Skilled Nursing Facilities, Intermediate Care Facilities, Nursing Facilities-Mental ILL, Federally Qualified Health Centers (FQHC), Indian Health Service, Maternal Health Centers, Certified Nurse Midwife, Community Mental Health, Family Planning, Residential Care Facilities, and ICF/ID State and Community Based ICF/ID Providers

APPLIES TO: Managed Care, Fee-for-Service

FROM: Iowa Department of Human Services (DHS), Iowa Medicaid Enterprise (IME)

RE: Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: April 1, 2018

1. **New Drug Prior Authorization Criteria-** See complete prior authorization criteria under the [Prior Authorization Criteria tab](#)¹.

▪ **Age Edit Override – Codeine or Tramadol:**

An age edit override for codeine or tramadol is required for patients under 18 years of age. Payment will be considered under the following conditions:

1. Member is 12 years of age or older; and
2. Medication is not being prescribed to treat pain after surgery following tonsil and/or adenoid procedure for members 12 to 18 years of age; and
3. If member is between 12 and 18 years of age, member is not obese (BMI greater than 30kg/m²), does not have obstructive sleep apnea, or severe lung disease.

2. **Changes to Existing Prior Authorization Criteria-** *Changes are italicized.* See complete prior authorization criteria under the [Prior Authorization Criteria tab](#).

- **Angiotensin Receptor Blocker before ACE Inhibitor:** Existing PA criteria is removed.

¹ http://www.iowamedicaidpd.com/pa_criteria

▪ **Biologicals for Ankylosing Spondylitis:**

Prior authorization is required for biologicals used for ankylosing spondylitis. *Request must adhere to all FDA approved labeling.* Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. *Payment will be considered under the following conditions:*

- *Patient has documentation of an inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration; and*
- *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; and*
- *Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and*
- *Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*

In addition to the above:

Requests for TNF Inhibitors:

- *Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last five years of starting or resuming treatment with a biological agent; and*
- *Patient does 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 percent or less.*

Requests for Interleukins:

- *Medication will not be given concurrently with live vaccines.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

▪ **Biologicals for Arthritis:**

Prior authorization is required for biologicals used for arthritis. *Request must adhere to all FDA approved labeling.* Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. *Payment will be considered under the following conditions:*

- *Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and*

- *Patient has been* screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; *and*
- *Patient has* a diagnosis of rheumatoid arthritis (RA):
A trial and inadequate response to two preferred disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, 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; *or*
- *Patient has* a diagnosis of moderate to severe psoriatic arthritis:
A trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); *or*
- *Patient has* a diagnosis of moderate to severe juvenile idiopathic arthritis:
A trial and inadequate response to intraarticular glucocorticoid injections and the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); *and*

In addition to the above:

Requests for TNF Inhibitors:

- *Patient has* not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last five years of starting or resuming treatment with a biological agent; *and*
- *Patient does 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 percent or less.

Requests for Interleukins:

- *Medication will not be given concurrently with live vaccines.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

▪ **Biologicals for Inflammatory Bowel Disease:**

Prior authorization is required for biologicals used for inflammatory bowel disease. *Request must adhere to all FDA approved labeling.* Payment for non-preferred biologicals for inflammatory bowel disease will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *Payment will be considered under the following conditions:*

- *Patient has been* screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; *and*
- *Patient has been* screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; *and*

- *Patient has a diagnosis of Crohn's Disease – Payment will be considered following an inadequate response to two preferred conventional therapy including aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate; or*
- *Patient has a diagnosis of Ulcerative Colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine; and*

In addition to the above:

Requests for TNF Inhibitors:

- *Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last five years of starting or resuming treatment with a biological agent; and*
- *Patient does 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 percent or less.*

Requests for Interleukins:

- *Medication will not be given concurrently with live vaccines.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

▪ **Biologicals for Plaque Psoriasis:**

Prior authorization is required for biologicals used for plaque psoriasis. *Request must adhere to all FDA approved labeling.* Payment for non-preferred biologicals for plaque psoriasis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. *Payment will be considered under the following conditions:*

- *Patient has documentation of an inadequate response to phototherapy, systemic retinoids (oral isotretinoin), methotrexate, or cyclosporine; and*
- *Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and*
- *Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*

In addition to the above:

Requests for TNF Inhibitors:

- *Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last five years of starting or resuming treatment with a biological agent; and*

- *Patient does 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 percent or less.*

Requests for Interleukins:

- *Medication will not be given concurrently with live vaccines.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated

▪ **Buprenorphine/Naloxone:**

Prior authorization is required for oral 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 three months. Requests for maintenance doses above 16mg per day will not be considered on a long-term basis. Concomitant use with opioids, or tramadol and hypnotics will be prohibited. ~~Benzodiazepines will be allowed up to a cumulative 30 days per 12-month period.~~ Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. Requests for surgically implanted buprenorphine products will not be considered through the pharmacy benefit and should be directed to the member's medical benefit. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of opioid dependence and *meets the FDA approved age*; 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. *Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances; and*
5. 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; AND
6. *A treatment plan is provided for patients taking buprenorphine in combination with a benzodiazepine or central nervous system (CNS) depressant, including:*
 - *Documentation patient has been educated on the serious risks of combined use;*
 - *A plan to taper the benzodiazepine or CNS depressant to discontinuation, if possible;*
 - *Consideration of alternate anxiety or insomnia treatment options when the benzodiazepine or CNS depressant is used for anxiety or insomnia; and*
 - *Other prescribers involved in the care of the patient are aware of the patient's use of buprenorphine; AND*
7. Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant.

8. Requests for *single ingredient* buprenorphine will only be considered for pregnant patients.

Requests for renewal must include:

1. An updated treatment plan *documenting the following*:
 - a. Consideration of a medical taper to the lowest effective dose based on a self-assessment scale *and*
 - b. *Assessment of concomitant benzodiazepine or CNS depressant use (if applicable) as outlined above, AND*
2. Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances since the last prior authorization request, *AND*
3. Documentation of a current, negative drug screen, *AND*
4. Documentation the patient has been compliant with office visits and counseling/psychosocial therapy visits, *AND*
5. Documentation the patient is not using transmucosal buprenorphine with the buprenorphine implant.

▪ **Immunomodulators – Topical:**

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 *one* preferred medium to high potency topical corticosteroid, *except on face or groin*.

▪ **Ivacaftor (Kalydeco):**

Prior authorization is required for Kalydeco™ (ivacaftor). Payment will be considered for patients when the following criteria are met:

1. Patient is two years of age or older; and
2. ~~*Patient* has a diagnosis of cystic fibrosis; and *with one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, and R117H as detected by a FDA-cleared CF mutation test; and*~~
3. ~~*Patient has one of the CFTR gene mutations as indicated in the FDA approved label as detected by an FDA-cleared CF mutation test; and*~~
4. Prescriber is a CF specialist or pulmonologist; and
5. Baseline liver function tests (AST/ALT) and FEV₄, if age appropriate, are provided.
6. ~~*Patient does not have one of the following infections: Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abscessus.*~~

If the criteria for coverage are met, an initial authorization will be given for three months. Additional approvals will be granted for six months at a time if the following criteria are met:

1. Adherence to ivacaftor therapy is confirmed; and

- ~~2. Response to therapy is documented by prescriber (e.g., improved FEV₁ from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and~~
3. Liver function tests (AST/ALT) are assessed every three months during the first year of treatment and annually thereafter.

▪ **Lidocaine Patch:**

Prior authorization is required for topical lidocaine patches. Payment will be considered *only for cases in which there is* a diagnosis of pain associated with post-herpetic neuralgia. ~~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.

▪ **Sacubitril/Valsartan (Entresto):**

Prior authorization is required for valsartan/sacubitril (Entresto™). Requests above the manufacturer recommended dose will not be considered. Payment will be considered for patients when the following criteria are met:

- ~~4. Patient is currently tolerating treatment with an ACE inhibitor or angiotensin II receptor blocker (ARB) at a therapeutic dose, where replacement with valsartan/sacubitril is recommended to further reduce morbidity and mortality~~
~~previous trial and therapy failure or intolerance to an ACE inhibitor at a maximally tolerated dose; and~~
- ~~5. Patient has documentation of a previous trial and therapy failure or intolerance to an angiotensin II receptor blocker (ARB); and~~

~~If the criteria for coverage are met, initial authorization will be given for 3 months. Requests for continuation of therapy may be provided if prescriber documents adequate response to therapy.~~

▪ **Topical Acne and Rosacea Products:**

Prior authorization (PA) is required for topical acne agents (topical antibiotics and topical retinoids) and topical rosacea agents. Payment for topical acne and topical rosacea agents will be considered under the following conditions:

1. Documentation of diagnosis.
2. For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid ~~for moderate to severe acne.~~

3. Point of Sale Billing Issues:

Pursuant to 441 Iowa Administrative Code 78.2(6), when it is not therapeutically contraindicated, the prescriber should prescribe a quantity of prescription medication sufficient for a month's supply. Contraceptives may be prescribed in three month quantities.

Pharmacies must bill once each month for the month's supply, or once every three months for the three month supply of contraceptives.

4. Preferred Brand Name Drugs on the PDL-Pharmacy Clarification

When a status change occurs for a previously preferred brand name drug to non-preferred status, up to a *minimum* of 30 days transition period is given to pharmacies to help utilize existing brand name product in stock in an effort to decrease a pharmacy's remaining brand name drug inventory (see PDL comment section regarding transition periods exceeding 30 days). If additional stock remains beyond this time period, pharmacies may call the POS Helpdesk at 877-463-7671 or 515-256-4608 (local) to request an override for the non-preferred brand name drug with a recent status change.

5. DUR Update: The latest issue of the Drug Utilization Review (DUR) Digest is located at the [Iowa DUR website](#)² under the "Newsletters" link.

We encourage providers to go to the [PDL website](#)³ to view all recent changes to the PDL. If you have questions, please contact the Pharmacy Prior Authorization Helpdesk at 877-776-1567 or 515-256-4607 (local in Des Moines) or e-mail info@iowamedicaidpdl.com.

² <http://www.iadur.org/>

³ <http://www.iowamedicaidpdl.com/>