Department of HUMAN SERVICES

INFORMATIONAL LETTER NO. 2291-MC-FFS

DATE: November 23, 2021

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, ICF/ID State and Community Based ICF/ID Providers, and Physician Assistants

APPLIES TO: Managed Care (MC), Fee-for-Service (FFS)

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

RE: January 2022 Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: January 1, 2022

1. **Changes to the Preferred Drug List (PDL) Effective January 1, 2022.** Refer to the PDL website[1] to review the complete PDL.

Preferred	Non-Preferred	Non-Recommended
Aimovig[1]	Aemcolo	Fotivda[1]
Avita Gel[1]	Arcalyst	Lumakras[1]
Beyaz	Arformoterol	Orgovyx[1]
Camrese	Azstarys[1]	Prezista
Camrese Lo	Bepotastine	Tepmetko[1]
Cleocin Vaginal Cream	Bevespi Aerosphere	Truseltiq[1]
Clindamycin/Benzoyl Peroxide[1]	Bonjesta	Ukoniq[1]
Clonidine ER Tablets[2]	Brexafemme	
Diclegis	Brinzolamide	
Dovato	Bronchitol[1]	
Dyanavel XR[5]	Buprenorphine Buccal Film[1]	

[1] http://www.iowamedicaidpdl.com/

Emtricitabine/tenofovir	Bylvay	
Elidel[1]	Cayston	
Epclusa 200-50mg tab[4]	Clobetex[1]	
Esperoct	Descovy[3]	
Gamastan S/D	Dojolvi	
Gammaked	Droxidopa	
Harvoni Oral Packet 33.75-150mg[6]	Dulera	
Humulin 70/30 KwikPen	Elepsia XR[1]	
Humulin 70/30 Vial	Empaveli	
Idelvion	Enalapril Oral Solution	
Imitrex Nasal Spray[1]	Epogen[1]	
Incruse Ellipta	Etravirine	
Insulin lispro junior KwikPen	Exservan[1]	
Insulin lispro protamine mix pen	Fluticasone/ salmeterol	
Kineret[1]	Formoterol Neb Solution	
Kloxxado	Gemtesa	
Levonorg-Eth Est Tab 0.15-0.03 MG (84) & Eth Est Tab 0.01 MG (7) (generic Seasonique)	Gimoti[1]	
Levonorg-Eth Est Tab 0.1-0.02 MG (84) & Eth Est Tab 0.01 MG (7) (generic LoSeasonique)	Humalog Cartridge	
Lo Loestrin FE	Humalog Junior KwikPen	
LoSeasonique	Humalog KwikPen	
M-Natal Plus	Humalog KwikPen Mix 75/25	
Minastrin 24 Chew FE	Ibuprofen/famotidine	
Mircera[1]	Kerendia	
Norethindrone & Ethinyl Estradiol-Fe Chew Tab 0.8 MG-25 MCG (generic Generess FE)	Kitabis Pak	
Norethindrone Ace-Ethinyl Estradiol-FE Tab 1 MG-20 MCG (24) (generic Loestrin 24 FE)	Lupkynis	

Norethindrone Ace-Eth Estradiol-FE Chew Tab 1 MG-20 MCG (24) (generic Minastrin 24 Chew FE)	Myfembree[1]	
Ofev[1]	Nextstellis	
Ondansetron Oral Solution[1]	Nivestym[1]	
Oriahnn[1]	Nurtec ODT[7]	
Praluent[1]	Nuvessa	
Repatha[1]	Nuwiq[3]	
Se-natal-19 Tablets	Nyvepria[1]	
SPS Suspension	Ozobax[1]	
Stiolto Respimat	Pimecrolimus Cream[1]	
Striverdi Respimat	Ponvory[1]	
Toujeo Max SoloStar	Pregabalin ER[1]	
Toujeo SoloStar	Prezcobix[3]	
Triumeq	ProAir RespiClick	
Tyblume	Qdolo[1]	
Virt-C DHA Capsules	Qelbree[1]	
Vp-pnv-dha Capsules	Reltone	
Xifaxan[1]	Rimantadine	
Xigduo XR	Sevenfact	
Yasmin	Sovaldi 200mg Tablets[1]	
Yaz	Sumatriptan Nasal Spray[1]	
Zegalogue[8]	Sunitinib[1]	
Zolmitriptan Nasal Spray[1]	Tiopronin	
Zolmitriptan Tablets[1]	Truvada	
	Twirla	
	Vyvanse[1]	
	Xolair Prefilled Syringe[1]	
	Zafemy	
	Zokinvy	
	Zomig Nasal Spray[1]	

[1] Clinical PA criteria apply
[2] 6 through 17 years of age
[3] Grandfather established users
[4] 6-11 years of age and 17-45kg
[5] 6-9 years of age
[6] 3 through 5 years of age and < 17kg for genotype 1,4,5 & 6
[7] Non-preferred for prophylaxis; Preferred for treatment

[8] Step through preferred reconstitution product

2. **Pharmacy Benefit Policy Changes –** Effective January 1, 2022, coverage for the drugs listed below will be removed under the pharmacy benefit. Coverage will continue, however, to be available through the medical benefit for albumin human, papaverine injection solution and Zoladex subcutaneous implant.

3. **New Drug Prior Authorization (PA) Criteria –** See complete PA criteria under the Prior Authorization Criteria tab[2].

- **Non-Biologic Agents for Ulcerative Colitis:**
  PA is required for select non-biologicals for ulcerative colitis (UC). Payment for non-preferred select non-biologics for UC may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent(s). Payment will be considered under the following conditions:
  1. Patient has a diagnosis of moderately to severely active UC and
  2. Request adheres to all Food and Drug Administration (FDA)-approved labeling for indication, including age, dosing, and contraindications; and
  3. A documented trial and inadequate response to two preferred conventional therapies (immunomodulators) including aminosalicylates and azathioprine/6-mercaptopurine; and
  4. A documented trial and inadequate response with a preferred biological DMARD; and
  5. Will not be taken concomitantly with immunomodulators or biologic therapies.

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

- **Vericiguat (Verquvo):**
  PA is required for vericiguat (Verquvo). Payment will be considered under the following conditions:
  1. Patient has a diagnosis of symptomatic chronic heart failure (NYHF class II-IV) with a left ventricular ejection fraction (LVEF) ≤ 45%; and
  2. Patient meets one of the following:
     a. Recent hospitalization for heart failure (within the last 6 months); or
     b. Recent need for outpatient intravenous diuretics (within the last 3 months); and
  3. Patient is within the FDA labeled age for indication; and
  4. Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least one month after the last dose; and

[2] http://www.iowamedicaidpdl.com/pa_criteria

5. Will not be used concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g. riociguat) or phosphodiesterase type 5 (PDE-5) inhibitors (e.g. sildenafil, tadalafil, vardenafil); and
6. Documentation of prior or current therapy, at a maximally tolerated dose, with one drug from each category below:
    a. Renin-angiotensin system inhibitor (angiotensin converting enzyme [ACEI], angiotensin receptor blocker [ARB], or angiotensin receptor-neprilysin inhibitor [ARNI]); and
    b. Evidence-based beta-blocker (carvedilol, metoprolol succinate, or bisoprolol); and
7. Is dosed based on FDA-approved dosing; and
8. Initial requests for Verquvo 2.5 mg and 5 mg tablets will be limited to one 14-day supply for each strength.

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

- **Viloxazine (Qelbree):**
  PA is required for viloxazine (Qelbree). Payment will be considered under the following conditions:
  1. Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and
  2. Patient is between 6 and 17 years of age; and
  3. Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational) and
  4. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred amphetamine stimulant; and
  5. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred methylphenidate stimulant; and
  6. Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine; and
  7. Is dosed based on FDA-approved dosing, and dose does not exceed 400 mg per day; and
  8. Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD.

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

4. Changes to Existing PA Criteria – *Changes are italicized or stricken.* See complete PA criteria under the Prior Authorization Criteria tab[3].

- **Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral [formerly Elagolix Products]:**
  PA is required for *oral gonadotropin-releasing hormone (GnRH) antagonists*. *Payment for non-preferred oral GnRH antagonists may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent.* Payment will be considered for patients when the following is met:
  3. Request adheres to all FDA-approved labeling for requested drug, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
  ~~4. Patient does not have severe hepatic impairment; and~~
  ~~5. Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine and gemfibrozil); and~~
  7. Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) *or relugolix, estradiol, norethindrone acetate (Myfembree)* will be considered under the following conditions:

- **Omalizumab (Xolair):**
  PA is required for omalizumab *(*Xolair*) prefilled syringe*. *Requests for omalizumab (Xolair) lyophilized powder for reconstitution will not be considered through the pharmacy benefit.* Payment for omalizumab *(*Xolair*) prefilled syringe* will be *considered for FDA-approved and compendia indications under the following conditions*:

  1. *Patient meets the FDA-approved age; and*
  2. Therapy will be initiated in a healthcare setting, under the guidance of a healthcare provider, where the patient can be closely observed for anaphylaxis and safety of therapy has been established after a minimum of 3 doses of omalizumab; and
  3. The healthcare provider has determined self-administration with omalizumab is appropriate based on careful assessment of risk for anaphylaxis and mitigation strategies, as outlined in the label; and
  4. Dose follows the FDA-approved dosing for indication; and
  5. Prescriber is an allergist, *dermatologist,* immunologist, *otolaryngologist* or pulmonologist; and
  6. Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of *omalizumab (*Xolair*); and*
  7. *Prescriber and dispensing pharmacy will educate patient on proper storage and administration. Improperly stored medications will not be replaced.*

[3] http://www.iowamedicaidpdl.com/pa_criteria

Moderate to Severe Persistent Asthma

1. Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and
~~2. Patient is 6 years of age or older; and~~
~~3. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and~~
4. Pretreatment IgE level is within the following range:
    a. Adults and adolescent patients 12 years of age or older - 30 IU/mL to 700 IU/mL; or
    b. Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and
5. Patient's weight is within the following range:
    a. Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; or
    b. Pediatric patients 6 to less than 12 years of age - 20 kg to 150 kg; and
6. History of positive skin or RAST test to a perennial aeroallergen; and
~~7. Prescriber is an allergist, immunologist, or pulmonologist; and~~
8. Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, AND a leukotriene receptor antagonist, and is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy; and
9. Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. *Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*
~~10. Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of Xolair®.~~

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to *omalizumab (*Xolair*)* therapy and for patients who do not continue concurrent use with a high dose corticosteroid, long-acting beta-agonist, and leukotriene receptor antagonist.

Chronic Idiopathic Urticaria

1. Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and
~~2. Patient is 12 years of age or older; and~~
~~3. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and~~
4. Patient has documentation of a trial and therapy failure with at least one preferred second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and

5. Patient has documentation of a trial and therapy failure with at least one preferred first-generation antihistamine; and
6. Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and
7. Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.

If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy. *Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy.*

Nasal Polyps

1. *Patient has a diagnosis of nasal polyps; and*
2. *Pretreatment IgE level is within the following range:*
   a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 1500 IU/mL; and*
3. *Patient's weight is within the following range:*
   a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; and*
4. *Patient has documentation of an adequate trial and inadequate response with at least two nasal corticosteroids at a maximally tolerated dose; and*
5. *Will be used concurrently with a nasal corticosteroid; and*
6. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*

If criteria for coverage are met, the initial authorization will be given for 24 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 omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a nasal corticosteroid.

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

- **Topical Acne and Rosacea Products:**
  PA is *not* required for *preferred* topical acne agents (topical antibiotics and topical retinoids) *for members under 21 years of age*. *PA is required* for *preferred topical acne agents for members 21 years or older,* non-*preferred* topical acne *agents* and *all* topical rosacea agents*. Payment* will be considered under the following conditions:

~~7. Trial and therapy failure with a preferred topical antipsoriatic agent will not be required for the preferred tazarotene (Tazorac) product for a psoriasis diagnosis.~~

5. Point of Sale Billing Updates:

ProDUR Quantity Limits: The following quantity limit edits will be implemented. A comprehensive list of all quantity limit edits appears on the Quantity Limit Chart[4].

Drug Product	Quantity	Days Supply
Qelbree 100MG	30	30
Qelbree 150MG & 200MG	60	30

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

We encourage providers to go to the PDL website[6] to view all recent changes to the PDL. If you have questions, please contact the Pharmacy Prior Authorization Helpdesk at 877-776-1567, locally at 515-256-4607, or by e-mail at info@iowamedicaidpdl.com.

[4] http://www.iowamedicaidpdl.com/billing_quantity_limits
[5] http://www.iadur.org/
[6] http://www.iowamedicaidpdl.com/