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MEMORANDUM

- TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers
- FROM: Cynthia Neuhofel, Pharm.D. Division of Medical Services Pharmacy Program
- DATE: February 12, 2025
- SUBJ: AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR Board January 15, 2025 meeting for the following:

Preferred Drug List Full Review: Glucagon agents, GLP-1 agonists, uterine disorder agents, Duchenne Muscular Dystrophy agents, ulcerative colitis agents
Preferred Drug List Abbreviated Review: Alpha glucosidase inhibitors, DPP-4 inhibitors, meglitinides, metformin products, SGLT-2 inhibitors, sulfonylureas, thiazolidinediones, amylin analogues, antiemetics, non-sedating antihistamines, intranasal rhinitis
Manual Review PA Criteria: Nemluvio® (nemolizumab-ilto), Miplyffa[™] (arimoclomol citrate), Aqneursa[™] (levacetylleucine), Hympavzi[™] (marstacimab-hncq), Vyalev[™] (foscarbidopa/foslevodopa), Duvyzat[™] (givinostat), Lodoco® (colchicine), Yorvipath® (palopegteriparatide), Furoscix® (furosemide)
Updates: Clean up manual review meds in PA criteria document, update general medication policy

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I. ANNOUNCEMENTS

1) **QUARTERLY NEWSLETTER**

As a service to our providers, we publish a quarterly provider newsletter with some updates for the Medicaid program and educational materials. The quarterly newsletter is in addition to this DUR Board provider memorandum. Archived newsletters can be found on the Prime Therapeutics State Government Solutions portal under the pharmacy tab. <u>https://ar.primetherapeutics.com/provider-documents</u>

The January 2025 quarterly newsletter can be found with the following link. <u>https://ar.primetherapeutics.com/documents/d/arkansas/arkansas-medicaid-quarterly-newsletter-january-2025-final</u>

2) RECENT MEDICAL BILLING UPDATE FOR 340B PROVIDERS

CMS has end dated modifier JG (340B Acquired Drug) as of 12/31/2024 as part of the 2025 HCPCS Annual Updates. When billing for dates of service 1/1/2025 and forward, Arkansas Department of Human Services will no longer pay 340B acquired drug claim details when billed with modifier JG.

Beginning with dates of service 1/1/2025, the appropriate modifiers to appended for 340B acquired drug claim details are:

- TB (340B Drugs)
- U7 (Orphan Drugs)
- U7 UA (All other drugs purchased outside of the 340B program)

For more information, please reference the CMS Publication MLN 4800856 at <u>humanservices.arkansas.gov/u/340b</u>

Any claim adjustments needed due to modifier JG being termed will be the responsibility of the provider. All claim submissions and adjustments should be received prior to the 365-day filing deadline.

3) <u>PREFERRED DRUG LIST</u> PDL UPDATE EFFECTIVE APRIL 1, 2025

NOTE: Bolded medications indicate a change from the previous preferred drug list or PA status.

Non-preferred agents require prior authorization submission. Prescribers with questions on how to obtain a PA should call the Prime Therapeutics State Government Solutions Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions Help Desk at 1-800-424-7976. Any PA request for off-label use will be reviewed on a case-by-case basis.

A. Classes with full clinical review

1. Glucagon Agents

Preferred Agents

- Baqsimi® (glucagon) intranasal powder
- Proglycem® (diazoxide) suspension—BRAND ONLY
- Zegalogue® (dasiglucagon) pre-filled syringe and autoinjector

Preferred Agent with Criteria

• Gvoke® (glucagon) pre-filled syringe and autoinjector

Point-of-sale approval criteria for Gvoke® pre-filled syringe and autoinjector

- Beneficiary is 2-5 years of age.
- If the beneficiary does not meet the age limitation, a prior authorization request is needed from the prescriber.

Non-preferred Agents

- Diazoxide suspension (generic for Proglycem®)
- Glucagon 1 mg emergency kit
- Gvoke® (glucagon) vial

2. GLP-1 Agonists

Updating the preferred drug list for the GLP-1 agonists has been delayed. The update may be delayed until July 1, 2025. If the update can be implemented before July 1, 2025, a 30-day notice will be given through a special memorandum.

3. GnRH Receptor Antagonists (New PDL Class)—i.e., uterine disorders

Preferred Agents with Criteria (manual review)

- Myfembree® tablet (relugolix, estradiol, and norethindrone acetate)
- Oriahnn® capsule (elagolix, estradiol, and norethindrone acetate & elagolix)
- Orilissa® tablet (elagolix)

Non-preferred Agents

None

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia

- Beneficiary must be prescribed **ONE** of the following medications with corresponding indications:
 - o Orilissa
 - Moderate to severe pain associated with endometriosis
 - o Oriahnn
 - Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women
 - o Myfembree
 - Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women
 - Moderate to severe pain associated with endometriosis in premenopausal women
- Attestation that beneficiary of reproductive potential will use effective non-hormonal contraception during treatment and for 1 week after discontinuing therapy
- Beneficiary must have tried and failed at least 2 of the following treatment options with at least a 3-month history (unless documentation of contraindication is provided):
 - NSAIDs and/or acetaminophen usage (for endometriosis associated pain)
 - Contraceptives (i.e., combined estrogen-progestin treatments include combined oral contraceptive pills, transdermal patches, and vaginal rings)
 - Progesterone-only therapy (e.g., medroxyprogesterone, norethindrone, dienogest)
 - Intrauterine device
- Beneficiary should not be approved or continue the medication if meet one of the following:
 - o Postmenopausal
 - o Pregnant
 - Known osteoporosis because of risk for further bone loss (T-score <-1.0 SD)
 - Severe hepatic impairment (Child-Pugh C); dose modifications may be needed for moderate hepatic impairment
 - Requires concomitant organic anion transporting polypeptide (OATP) 1B1 (a hepatic uptake transporter) (e.g., cyclosporine and gemfibrozil)
 - History of major depression or PTSD in the last 2 years OR history of a major psychiatric disorder (i.e., schizophrenia or bipolar) OR history of suicide attempt in the last year
 - Exceeds the following dosing:
 - ORILISSA
 - 150 mg once daily for 24 months-- no hepatic impairment or dyspareunia
 - 200 mg twice daily for 6 months—has dyspareunia
 - 150 mg once daily for 6 months—has moderate hepatic impairment (Child-Pugh B)
 - MYFEMBREE—1 tablet daily for maximum of 24 months
 - ORIAHNN—1 capsule twice daily for maximum of 24 months
 - Request for ORILISSA
 - Chronic pelvic pain that is not caused by endometriosis (e.g., pelvic inflammatory disease, inflammatory bowel disease, ovarian cysts)
 - Request for ORIAHNN or MYFEMBREE
 - High risk of arterial, venous thrombotic, or thromboembolic disorders which is defined as having at least one of the following
 - woman over 35 years of age who smoke
 - current or history of deep vein thrombosis or pulmonary embolism
 - vascular disease (e.g., cerebrovascular disease, coronary artery disease, peripheral vascular disease)
 - thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
 - inherited or acquired hypercoagulopathies

- uncontrolled hypertension
- headaches with focal neurological symptoms or have migraine headaches with aura if over age 35
- Current or history of breast cancer or other hormonally-sensitive malignancies, and with increased risk of hormonally-sensitive malignancies
- Undiagnosed abnormal uterine bleeding
- History of heavy bleeding associated with uterine fibroids that has not caused anemia (hemoglobin level ≤ 12 g/dL)
- Concomitant use with oral P-gp inhibitors for MYFEMBREE
- Prescriber must submit the following:
 - Name of the medication being requested
 - \circ $\;$ Current chart notes with symptom history
 - o Documentation of previous therapies tried with duration and response
 - Confirmation of diagnosis with pelvic exam results and imaging/biopsy results (e.g., transvaginal US, MRI, laparoscopy, CT scan)
 - Current labs including CBCs and LFTs
 - Confirmation of negative pregnancy status (i.e., current negative pregnancy test, beginning medication within 7 days of onset of menses, or tubal ligation)
 - Letter of medical necessity outlining the need for one of these medications over other treatment options ((i.e., OTC pain medications, hormonal contraception, progestin therapy, and surgery)
 - If requesting a non-preferred medication, provide the necessity of the chosen medication over the preferred option(s).

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate improvement of symptoms (i.e., reduction in endometriosis related pain, decrease in heavy menstrual bleeding and/or improvement in hemoglobin)
- Beneficiary remains free from hepatic impairment, osteoporosis, psychiatric disorders, and pregnancy
- Beneficiary has not surpassed the maximum treatment duration as noted in the package insert
- Beneficiary of reproductive potential remains on non-hormonal contraception
- Prescriber must submit the following:
 - Current chart notes with documentation of current symptoms
 - Current labs including CBCs and LFTs
 - Documentation of negative pregnancy status

4. <u>Ulcerative Colitis Agents (New PDL Class)—excluding biologics</u>

Preferred Agents

- Apriso® capsule (mesalamine ER)
- Mesalamine suppository (generic for Canasa®)
- Pentasa® capsule (mesalamine ER)
- Sulfasalazine tablet (generic for Azulfidine®)
- Sulfasalazine DR tablet (generic for Azulfidine EN-tab®)

Preferred Agent(s) with Criteria

• Budesonide ER tablet (generic for Uceris®)

UCERIS [®]extended-release tablets are indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis.

The recommended dosage for the induction of remission in adult patients with active, mild to moderate ulcerative colitis is 9 mg taken orally once daily in the morning with or without food for up to 8 weeks.

Point-of-sale approval criteria for budesonide ER 9 mg tablets

- Beneficiary must have a billed diagnosis of ulcerative colitis in the past 2 years; AND
- Beneficiary must have a pharmacy claim in their Arkansas Medicaid history over the last 186 days for one of following:
 - Oral or rectal mesalamine
 - o Sulfasalazine
- Beneficiary will be limited to 2 claims of budesonide ER 9 mg tablets every 186 days for a total of 60 tablets.

For beneficiaries not meeting the above point-of-sale approval criteria, prior authorization approvals will be for 2 months only as indicated in the package insert dosing.

Non-preferred Agents

- Azulfidine® tablet (sulfasalazine)
- Azulfidine® EN-tab (sulfasalazine DR)
- Balsalazide capsule (generic for Colazal®)
- Budesonide foam (generic for Uceris®)
- Canasa® suppository (mesalamine)
- Colazal® capsule (balsalazide)
- Delzicol® capsule (mesalamine DR)
- Dipentum® capsule (olsalazine)
- Lialda® tablet (mesalamine DR)
- Mesalamine DR tablet (generic for Asacol HD®)
- Mesalamine DR capsule(generic for Delzicol®)
- Mesalamine DR tablet (generic for Lialda®)
- Mesalamine enema (generic for sfRowasa®)
- Mesalamine ER capsule (generic for Apriso®)
- Mesalamine ER capsule (generic for Pentasa®)
- Mesalamine kit (generic for Rowasa®)
- Rowasa® kit (mesalamine)
- sfRowasa® enema (mesalamine)
- Uceris® foam (budesonide)
- Uceris® tablet (budesonide)

5. Duchenne Muscular Dystrophy Agents (New PDL Class)

Preferred Agents with Criteria (manual review)

- Emflaza® suspension (deflazacort)—BRAND ONLY
- Emflaza® tablet (deflazacort)—BRAND ONLY

Non-preferred Agents

- Agamree® suspension (vamorolone)
- Deflazacort suspension (generic for Emflaza®)
- Deflazacort tablet (generic for Emflaza®)
- Duvyzat[™] suspension (givinostat)

Criteria for Emflaza®/deflazacort and Agamree® are not changing other than any nonpreferred requests require the medical necessity over brand name Emflaza®.

DUVYZAT (givinostat) APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with Duchenne Muscular Dystrophy (DMD) <u>OR</u> a diagnosis consistent with any new FDA-approved indication. Any off-label requests will be reviewed on a case-by-case basis.
- Prescribed by a provider who specializes in the treatment of DMD and/or neuromuscular disorders
- Beneficiary must have been stable on prednisone, deflazacort, or vamorolone for at least 6 months unless there is a documented contraindication
- Beneficiary will continue corticosteroid therapy concomitantly unless contraindicated
- Beneficiary should not be approved or continue the medication if meet one of the following:
 - Baseline platelet count less than 150 x 10⁹/L
 - Triglycerides remain elevated despite adequate dietary intervention and dosage adjustment
 - Previous gene therapy for the treatment of DMD (e.g., Elevidys®)
 - Currently non-ambulatory
 - Prescriber must submit the following:
 - o Current chart notes
 - o Documentation of the mutation in the dystrophin gene
 - Previous therapies tried with timeframe and response
 - Current labs including platelets and lipids
 - Baseline ECG results if has underlying cardiac disease or taking concomitant medications that cause QT prolongation
 - o Current weight
 - Dose requested
 - Baseline assessment of ambulatory function to be used throughout treatment for consistent monitoring (e.g., Time to Stand Test (TTSTAND), 4-stair climb (4SC) time, North Star Ambulatory Assessment (NSAA))
 - Documentation that the beneficiary is currently receiving, or planning to receive, physical therapy and provide physical therapy notes
 - Letter of medical necessity with a significant clinical reason specific to the beneficiary that DUVYZAT is needed over the preferred medications and of medications available as a medical claim (i.e., eteplirsen, golodirsen, casimersen, and viltolarsen)

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant with therapy (defined as 75% utilization)
- Beneficiary demonstrates a positive response with either clinical improvement or a decrease in the rate of function decline compared to baseline
- Beneficiary lacks clinically significant or intolerable adverse effects related to treatment (i.e., platelets remain >150 x 10⁹/L)
- Prescriber must submit the following:
 - Current chart notes with documentation of response to therapy
 - Current labs including platelets and lipids
 - Attestation that the beneficiary continues physical therapy

QUANTITY EDITS:

420 mL (3 bottles)/35 days

B. Classes with abbreviated review

6. Alpha Glucosidase Inhibitors

Preferred agents: Alpha Glucosidase Inhibitors

• Acarbose (generic for Precose®)

Non-Preferred agents: Alpha Glucosidase Inhibitors

- Miglitol (generic for Glyset®)
- Precose® (acarbose)

7. DPP-4 Inhibitors

Preferred agents: DPP-4 Inhibitors (manual review)

- Janumet® (sitagliptin/metformin)
- Januvia® (sitagliptin)
- Saxagliptin (generic for Onglyza®)
- Tradjenta® (linagliptin)

Non-Preferred agents: DPP-4 Inhibitors

- Alogliptin (generic for Nesina®)
- Alogliptin/metformin (generic for Kazano®)
- Alogliptin/pioglitazone (generic for Oseni®)
- Glyxambi® (linagliptin/empagliflozin)
- Janumet® XR (sitagliptin/metformin extended release)
- Jentadueto® (linagliptin/metformin)
- Jentadueto® XR (linagliptin/metformin extended release)
- Kazano® (alogliptin/metformin)
- Nesina® (alogliptin)
- Oseni® (alogliptin/pioglitazone)
- Qtern® (saxagliptin/dapagliflozin)
- Saxagliptin/metformin ER (generic for Kombiglyze® XR)
- Sitagliptin (generic for Zituvio®)
- Sitagliptin/metformin (generic for Zituvimet®)
- Steglujan® (sitagliptin/ertugliflozin)
- Trijardy® XR (linagliptin/empagliflozin/metformin ER)
- Zituvimet® (sitagliptin)
- Zituvimet® XR (sitagliptin)
- Zituvio® (sitagliptin)

8. <u>Meglitinides</u>

Preferred agents: Meglitinides

- Nateglinide (generic for Starlix®)
- Repaglinide (generic for Prandin®)

Non-Preferred agents: Meglitinides

None

9. Metformins

Preferred agents: Metformins

- Metformin 500mg (generic for Glucophage®)
- Metformin 850mg (generic for Glucophage®)
- Metformin 1000mg (generic for Glucophage®)
- Metformin ER 500mg (generic for Glucophage XR®)
- Metformin ER 750mg (generic for Glucophage XR®)

Non-Preferred agents: Metformins

- Glumetza® (metformin ER)
- Metformin 625mg
- Metformin ER Gastric 500mg and 1000mg (generic for Glumetza®)
- Metformin ER Osmotic 500mg and 1000mg (generic for Fortamet®)
- Metformin solution (generic for Riomet®)
- Riomet® solution (metformin)

10. SGLT-2 Inhibitors

Preferred agents: SGLT-2 Inhibitors

- Farxiga® (dapagliflozin)—BRAND ONLY
- Jardiance® (empagliflozin)
- Synjardy® (empagliflozin/metformin)
- Xigduo® ER (dapagliflozin/metformin ER)—BRAND ONLY

Non-Preferred agents: SGLT-2 Inhibitors

- Dapagliflozin (generic for Farxiga®)
- Dapagliflozin/metformin ER (generic for Xigduo® ER)
- Inpefa® (sotagliflozin)
- Invokamet® (canagliflozin/metformin)
- Invokamet® XR (canagliflozin/metformin ER)
- Invokana® (canagliflozin)
- Segluromet[™] (ertugliflozin/metformin)
- Steglatro[™] (ertugliflozin)
- Synjardy® XR (empagliflozin/metformin ER)

11. Sulfonylureas

Preferred agents: Sulfonylureas

- Glimepiride 1 mg, 2 mg, 4 mg (generic for Amaryl®)
- Glimepiride/pioglitazone (generic for Duetact®)
- Glipizide (generic for Glucotrol®)
- Glipizide ER (generic for Glucotrol XL®)
- Glipizide/Metformin (generic for Metaglip®)
- Glyburide (generic for Diabeta®)
- Glyburide micronized (generic for Micronase®, Glynase®)
- Glyburide/Metformin (generic for Glucovance®)

Non-Preferred Agents: Sulfonylureas

- Duetact® (glimepiride/pioglitazone)
- Glimepiride 3 mg tablet
- Glucotrol XL® (glipizide)

12. Thiazolidinediones

Preferred agents: Thiazolidinediones

- Pioglitazone (generic for Actos®)
- Pioglitazone/metformin (generic for ActoPlus Met®)
- Pioglitazone/glimepiride (generic for Duetact®)

Non- Preferred agents: Thiazolidinediones

- ActoPlus Met® (pioglitazone/metformin)
- Actos® (pioglitazone)
- Duetact® (pioglitazone/glimepiride)

13. Amylin Analogues

Preferred agents: Amylin Analogues

None

Non-Preferred agents: Amylin Analogues

• Symlin® (pramlintide)

14. Antiemetics

Preferred agents with criteria

- Ondansetron HCI 4mg, 8mg tablet (generic for Zofran®)
- Ondansetron 4mg, 8mg oral-disintegrating tablet (generic for Zofran ODT®)
- Ondansetron 4mg/2ml preservative-free vial (generic for Zofran®)
- Ondansetron 40mg/20ml vial (generic for Zofran®)

Non-preferred agents

- Akynzeo® capsule (netupitant-palonosetron HCL)
- Aprepitant (generic for Emend®)
- Emend® (aprepitant)
- Granisetron (generic for Kytril®)
- Ondansetron 16 mg oral-disintegrating tablet
- Ondansetron 4mg/2ml ampule and syringe (generic for Zofran®)
- Ondansetron 4mg/5ml solution (generic for Zofran®)
- Sancuso® patch (granisetron)

15. Non-sedating Antihistamines

Preferred agents

- Cetirizine HCI 1 mg/ml solution, 10 mg swallow tablet (generic for Zyrtec®)
- Loratadine (generic for Claritin®)

Nonpreferred agents

- Cetirizine 5 mg swallow tablet, 5 and 10 mg chewable tablet (generic for Zyrtec®)
- Clarinex® (desloratadine)
- Desloratadine (generic for Clarinex®)
- Fexofenadine 180 mg tablet (generic for Allegra®)
- Levocetirizine (generic for Xyzal®)

16. Intranasal Rhinitis

Preferred Agents

- Azelastine nasal spray (generic for Astelin®, Astepro®)
- Fluticasone propionate nasal spray (generic for Flonase®)
- Ipratropium nasal spray (generic for Atrovent®)

Preferred agents with criteria

• Mometasone furoate nasal spray (generic for Nasonex®)

Point-of-Sale criteria for mometasone furoate nasal spray

- Beneficiary is 2-3 years of age
- If the beneficiary does not meet the age limitation, a prior authorization request is needed from the prescriber.

Non-Preferred Agents

- Azelastine/fluticasone nasal spray (generic for Dymista®)
- Budesonide nasal spray (generic for Rhinocort®)
- Dymista® nasal spray (azelastine/fluticasone)
- Flunisolide nasal spray (generic for Nasarel®, Nasalide®)
- Olopatadine nasal spray (generic for Patanase®)
- Omnaris® nasal spray (ciclesonide)
- Qnasl®, Qnasl Childrens® nasal spray (beclomethasone)
- Ryaltris® nasal spray (olopatadine/mometasone)
- Xhance® nasal spray (fluticasone)
- Zetonna[™] nasal spray (ciclesonide)

II. PRIOR AUTHORIZATION DRUG CRITERIA (NEW OR REVISED):

CRITERIA EFFECTIVE JANUARY 15, 2025

1. FUROSCIX (furosemide)

FUROSCIX utilization was reviewed by the DUR Board. The Board voted to keep the currently approved criteria as listed below.

APPROVAL CRITERIA

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with New York Heart Association (NYHA) Class III chronic heart failure and being treated for congestion due to fluid overload <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Must be prescribed by or in consultation with a cardiologist
- Beneficiary must have tried and failed oral furosemide (160 mg) and one of the following:
 - Torsemide (40 mg)
 - o Bumetanide (4 mg)
- Beneficiary must be adherent to CHF therapies (i.e., ACE/ARB, beta blockers, salt restrictions)
- Beneficiary must have documented recent weight gain and increased edema or other symptoms of extracellular volume expansion (e.g., jugular venous distention, pulmonary congestion or rales)
- Beneficiary must have had recent renal lab work done
- Prescriber must submit ALL of the following:
 - Current chart notes

- o Current and previous therapies for heart failure
- o Medical necessity over oral and IV furosemide and other diuretics class
- Current and baseline weight
- Confirmation that beneficiary has a history of at least one prior hospitalization or emergency department visit due to heart failure exacerbations and/or fluid overload, and the beneficiary is stable enough to avoid hospitalization at the time of administration
- Current labs
- Attestation that Furoscix® will be used short-term then transitioned back to oral diuretics as soon as practical.

RENEWAL REQUIREMENTS

- Beneficiary continues to have fluid overload
 - Prescriber must submit the following:
 - Current chart notes
 - Continued treatment plan for fluid overload
 - Current weight and description of edema

QUANTITY EDITS

#2 per claim

CRITERIA EFFECTIVE JANUARY 15, 2025

2. PA CRITERIA DOCUMENT UPDATE

The prior authorization (PA) criteria document contains many medications that have been missing specific review criteria and multiple medications that are no longer on the market. Therefore, this attached document has been approved to bring the PA criteria document up to date. The medications in this document will be added to the main PA criteria document.



MRD on document without criteria3.docx

The full PA criteria document can be found on the Prime Therapeutics website. <u>https://ar.primetherapeutics.com/documents/d/arkansas/ar_prescription_drug_program_pa_crit</u> <u>eria</u>

CRITERIA EFFECTIVE JANUARY 15, 2025

3. GENERAL MEDICATION POLICY UPDATE

The general medication policy has been updated to include language about off-label requests. <u>https://ar.primetherapeutics.com/documents/d/arkansas/arm-general-medication-coverage-policy-2025</u>

CRITERIA EFFECTIVE JANUARY 15, 2025

4. NEMLUVIO (nemolizumab-ilto) 30 mg injection

The DUR Board voted to update language in the Prurigo Nodularis and Atopic Dermatitis criteria based on Nemluvio® being added as a non-preferred product for these indications.

PRURIGO NODULARIS

Approval Criteria for Prurigo Nodularis (Dupixent® and Nemluvio®)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary must have a diagnosis of prurigo nodularis with widespread or recalcitrant disease OR has a comorbidity of moderate to severe atopic dermatitis
- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis/prurigo nodularis

- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- If the request is for a non-preferred medication, the beneficiary must have tried and failed the preferred biologic(s) with this indication before non-preferred options can be approved unless there is a patient specific contraindication to the preferred option(s)
- Beneficiary must have a trial and failure of topical medications and at a minimum must include (unless contraindicated or inappropriate for the patient's age):
 - At least ONE topical corticosteroid entity over a minimum of 60 days use with topical corticosteroids being "high" potency (Class-2) <u>OR</u> superpotent (Class-1) <u>OR</u> medium potency for children; AND
 - At least ONE trial of a topical calcineurin inhibitor (TCI) with either pimecrolimus or tacrolimus over a minimum of 30 days
- Prescriber must submit the following:
 - Current chart notes
 - Description of current status for baseline (i.e., BSA of nodules, peak pruritis Numeric Rating Scale (NRS), Investigator's Global Assessment (IGA)
 - Previous therapies tried
 - If no history of atopic dermatitis, provide documentation that other systemic causes for pruritis have been ruled out (i.e., chronic kidney disease, liver disease)

Continuation Criteria for Prurigo Nodularis

- Beneficiary must show continued positive treatment response with each PA request for continued prior approval with at least one of the following compared to baseline:
 - Decrease in pruritis; **OR**
 - Decrease in BSA impacted; **OR**
 - o Decrease in need for systemic or topical rescue treatment
- Prescriber must submit:
 - o Current chart notes
 - Current BSA and pruritis test scores (i.e., NRS, IGA)

IMMUNOMODULATORS, ATOPIC DERMATITIS (topicals and biologics)

PREFERRED AGENT(S)

• Tacrolimus ointment (generic for Protopic®)

PREFERRED AGENTS WITH CRITERIA (*specific manual review criteria)

- Adbry®* syringe and autoinjector (tralokinumab-ldrm)
- Dupixent®* syringe and pen (dupilumab)

NON-PREFERRED AGENTS WITH CRITERIA (*specific manual review criteria)

Note: Non-preferred agents require documentation of medical necessity over preferred agents in addition to other stated criteria.

- Cibinqo®* tablet (abrocitinib)
- Elidel® cream (pimecrolimus)
- Eucrisa® ointment (crisaborole)
- Nemluvio®* injection (nemolízumab-ilto)
- Opzelura®* cream (ruxolitinib)
- Pimecrolimus cream (generic for Elidel®)
- Protopic® ointment (tacrolimus)
- Rinvoq®* tablet (upadacitinib)

<u>APPROVAL CRITERIA FOR ATOPIC DERMATITIS</u> (Adbry®, Cibinqo®, Dupixent®, Nemluvio® and Rinvoq®)

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis
- Beneficiary has a documented diagnosis of moderate to severe atopic dermatitis with at least **ONE** of the following (baseline at time of biologic request):
 - Baseline impacted body surface area (BSA) $\ge 10\%$
 - Baseline Eczema Area and Severity Index (EASI) total score of ≥ 16

- Baseline weekly averaged peak pruritis Numeric Rating Scale (NRS) \geq 7
- Baseline Investigator's Global Assessment (IGA) score ≥ 3
- Baseline Scoring Atopic Dermatitis (SCORAD) score ≥ 25
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in the official Compendia
- Beneficiary has no therapeutic duplication with monoclonal antibodies or cytokine & CAM antagonists
- If the request is for a non-preferred medication, the beneficiary must have tried and failed the preferred biologic(s) with this indication before non-preferred options can be approved unless there is a patient specific contraindication to the preferred option(s)
- Beneficiary must have a trial and failure of topical therapy and at a minimum must include:
 - At least ONE topical corticosteroid entity over a minimum of 60 days use with topical corticosteroids being "high" potency (Class-2) OR superpotent (Class-1) for adults OR medium potency for children (unless contraindicated); AND
 - At least **ONE** trial of a topical calcineurin inhibitor (TCI) over a minimum of 30 days (i.e., pimecrolimus or tacrolimus)
- Prescriber must submit ALL of the following:
 - o Current chart notes
 - o Documentation of previous therapies with trial length of each medication
 - o BSA prior to topical/systemic therapies and current impacted BSA
 - o Baseline EASI, NRS, IGA and/or SCORAD and updated score with previous treatment
 - Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history
 - Letter of medical necessity over other treatment options for atopic dermatitis

CRITERIA EFFECTIVE JANUARY 15, 2025

5. AQNEURSA (levacetylleucine) 1 gm granule packet

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the
- manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of Niemann-Pick disease type C (NPC) with variants in the NPC1 or NPC2 genes with neurological manifestations (e.g., gait problems, ataxia, cognitive deterioration, or vertical gaze palsy) <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPD
- Beneficiary should not be approved or continue the medication if meet one of the following:
 - Weighs <15 kg
 - Pregnant
 - Dose requested does not match weight-based dosing found in the package insert
 - Prescribed Miplyffa[™] (arimoclomol) to be used concomitantly
 - Prescriber must submit the following:
 - Current chart notes
 - Previous therapies tried with response
 - Molecular genetic testing results confirming biallelic pathogenic variants in the NPC1 or NPC2 genes
 - Current weight and dose requested
 - Neurological symptoms for this specific patient
 - Negative pregnancy test results if applicable
 - Attestation that female beneficiary of reproductive potential has been counseled on the importance of effective contraception

RENEWAL REQUIREMENTS:

- Beneficiary remains compliant with therapy (defined as 75% utilization)
- Beneficiary demonstrates a positive response with a decrease or slowed progression in neurological symptoms compared to baseline
 - Prescriber must submit the following:
 - o Current chart notes
 - o Response to treatment with updated description of symptoms
 - Attestation that female beneficiary of reproductive potential has been counseled on the importance of continuing effective contraception and is not currently pregnant

QUANTITY EDITS:

#120/ 30 days

CRITERIA EFFECTIVE JANUARY 15, 2025

6. MIPLYFFA (arimoclomol citrate) 47 mg, 62 mg, 93 mg, & 124 mg capsule

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of Niemann-Pick disease type C (NPC) with variants in the NPC1 or NPC2 genes with neurological manifestations (e.g., gait problems, ataxia, cognitive deterioration, or vertical gaze palsy) and prescribed concomitant miglustat <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPD
- Beneficiary with eGFR ≥ 15 to < 50 mL/minute should decrease MIPLYFFA dose frequency
- Beneficiary should not be approved or continue the medication if meet one of the following:
 - Weighs <8 kg
 - Pregnant
 - o Dose requested does not match weight-based dosing found in the package insert
 - Prescribed Aqneursa™ (levacetylleucine) to be used concomitantly
 - eGFR < 15 mL/minute
 - Prescriber must submit the following:
 - Current chart notes
 - Previous therapies tried with response
 - Molecular genetic testing results confirming biallelic pathogenic variants in the NPC1 or NPC2 genes
 - Current labs including eGFR
 - Current weight and dose requested
 - Neurological symptoms for this specific patient
 - Negative pregnancy test results if applicable
 - Attestation that female beneficiary of reproductive potential has been counseled on the importance of effective contraception
 - Letter of medical necessity for the use over Aqneursa[™] (levacetylleucine) for this specific patient

RENEWAL REQUIREMENTS:

- Beneficiary remains compliant with therapy (defined as 75% utilization)
- Beneficiary demonstrates a positive response with a decrease or slowed progression in neurological symptoms compared to baseline
- Prescriber must submit the following:
 - Current chart notes
 - \circ $\,$ Response to treatment with updated description of symptoms $\,$
 - Attestation that female beneficiary of reproductive potential has been counseled on the importance of continuing effective contraception and is not currently pregnant

QUANTITY EDITS:

#90/30 days

CRITERIA EFFECTIVE JANUARY 15, 2025

7. HYMPAVZI (marstacimab-hncq) 150 mg injection

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary requires routine prophylaxis to prevent or reduce the frequency of bleeding episodes and is diagnosed with **one** of the following:
 - o hemophilia Ă (congenital factor VIII deficiency) without factor VIII inhibitors, or
 - hemophilia B (congenital factor IX deficiency) without factor IX inhibitors.
 - Beneficiaries must meet <u>one</u> of the following for confirming disease severity:
 - Severe disease with <1% of factor VIII or factor IX in blood while on factor products; OR
 - Moderate disease with 1-5% of factor VIII or factor IX in blood while on factor products with **ONE** of the following (prescriber must submit letter of medical necessity and chart notes to support):
 - History of spontaneous bleeding episodes into the central nervous system or other serious life-threatening bleed; OR
 - At least two (2) joint bleeds causing hemophilia-related joint damage; OR
 - Poor venous access; OR
 - High Factor VIII or Factor IX dose
- Request must be submitted by, or in consultation with, a hemophilia specialist or hemophilia treatment center
- Beneficiary should not be approved or continue the medication if meets one of the following:
 - Continues to receive prophylaxis Factor doses (e.g., FVIII, FIX, or bypassing agents)
 - Hympavzi[™] is ordered for breakthrough bleeding
 - Pregnant
- Prescriber must submit the following:
 - Chart notes for the last 24 weeks with summary of bleeding events
 - Previous therapies tried with timeline and response (prophylaxis and acute treatment)
 - o Current factor activity and annualized bleeding rate
 - Current labs including CBC
 - Negative pregnancy test results if applicable
 - Attestation that female beneficiary of reproductive potential has been counseled on the importance of effective contraception
 - Attestation that beneficiary has been counseled on proper technique on episodic treatment with factor VIII or factor IX products as needed for breakthrough bleeding episodes
 - Medical necessity over prophylaxis factor products and Hemlibra® for hemophilia A

RENEWAL REQUIREMENTS:

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a decrease in annualized bleeding rate compared to baseline
- Prescriber must submit the following:
 - Current chart notes
 - Current labs including CBC
 - Summary of bleeds since last PA

QUANTITY EDITS:

#8 /28 days

CRITERIA EFFECTIVE JANUARY 15, 2025

8. <u>VYALEV (foscarbidopa/foslevodopa) 120 mg/2400 mg injection</u>

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with advanced Parkinson's disease and experiencing continued motor fluctuations despite compliance on carbidopa/levodopa <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have demonstrated a previous response to levodopa but continue to have motor fluctuations with a minimum of 2.5 hours of "Off" time per day
- Prescriber must attest that patient/caregivers have been counseled on potential adverse effects that require monitoring that could require a dose reduction or discontinuation (i.e., impulsive behaviors, infusion site reactions, dyskinesia, and glaucoma)
- Beneficiary should not be approved or continue the medication if meet one of the following:
 - o Requires non-selective monoamine oxidase (MAO) inhibitor
 - Has a major psychiatric disorder
- Prescriber must submit the following:
 - Current chart notes
 - o Current symptoms of Parkinson's Disease
 - Average number of "Off" hours per day
 - Medical necessity over increasing the dose on long and short acting oral carbidopa/levodopa products

RENEWAL REQUIREMENTS:

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary demonstrates a decrease in "Off" hours compared to baseline
- Prescriber must submit the following:
 - Current chart notes
 - Documentation of response to therapy
 - Attestation that patient continues to be monitored for potential adverse reactions (i.e., impulsive behaviors, infusion site reactions, dyskinesia, and glaucoma)

CRITERIA EFFECTIVE JANUARY 15, 2025

9. LODOCO (colchicine) 0.5 mg tablet

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with atherosclerotic disease or have multiple risk factors for cardiovascular disease
- Beneficiary is currently taking standard of care treatment for chronic coronary disease (e.g., antiplatelet, anticoagulant, lipid-lower agent, beta blocker, renin-angiotensin inhibitor)
- Beneficiary should not be approved or continue the medication if meet one of the following:
 - Renal failure (CrCl <15 mL/minute); patients with renal impairment should be monitored
 - Severe hepatic impairment
 - Requires strong CYP3A4 inhibitors or P-gp inhibitors
 - Has pre-existing blood dyscrasias (i.e., myelosuppression, leukopenia,
 - granulocytopenia, thrombocytopenia, pancytopenia, and aplastic anemia)
 - Develops neuromuscular toxicity or rhabdomyolysis
- Prescriber must submit the following:
 - Current chart notes
 - Current labs including creatinine clearance and eGFR

- Previous therapies for atherosclerotic disease
- Letter of medical necessity over the use of colchicine 0.6 mg capsule or tablet

<u>NOTE: The Board voted to remove the POS edit for colchicine tablets and make it available</u> <u>without prior authorization.</u>

RENEWAL REQUIREMENTS:

- Beneficiary is compliant with therapy (defined as 75% utilization)
- Prescriber must submit the following:
 - o Current chart notes
 - Documentation of any change to cardiovascular status

QUANTITY EDITS: #30/30 days

CRITERIA EFFECTIVE JANUARY 15, 2025

10. YORVIPATH (palopegteriparatide) 168 mcg, 294 mcg, & 420 mcg injection

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with hypoparathyroidism
- Must be prescribed by, or consultation with, an endocrinologist, nephrologist or other specialist knowledgeable in treating hypoparathyroidism
- Beneficiary must not have adequate control of hypocalcemia with calcium and vitamin D supplements prior to approval
- Beneficiary must have a baseline albumin-corrected serum calcium of at least 7.8 mg/dL while using calcium and active vitamin D treatment
- Beneficiary should not be approved or continue the medication if meet one of the following:
 - At increased risk of osteosarcoma
 - Open epiphyses. YORVIPATH is not approved in pediatric patients
 - Metabolic bone diseases other than hypoparathyroidism, including Paget's disease of bone.
 - Unexplained elevations of alkaline phosphatase.
 - Bone metastases or a history of skeletal malignancies.
 - History of external beam or implant radiation therapy involving the skeleton.
 - Hereditary disorders predisposed to osteosarcoma
 - Has acute post-surgical hypoparathyroidism
 - Requested dose exceeds 30 mcg per day or dose requested requires more than 1 injection
 - Prescribed concomitant teriparatide (Forteo®)
 - Prescriber must submit the following:
 - Current chart notes
 - Documentation of previous therapies tried
 - Dose requested
 - Current labs including calcium, vitamin D, magnesium
 - Treatment plan that includes monitoring calcium levels 7-10 days after first dose and after any dose change of YORVIPATH, active vitamin D, or calcium supplements. For maintenance, labs should be checked at a minimum every 4-6 weeks or when patient experiences symptoms of hypocalcemia or hypercalcemia

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant with therapy including calcium and vitamin D supplements if prescribed concomitantly (compliance defined as 75% utilization)
- Beneficiary has a positive response with albumin-corrected serum calcium within normal limits

- If labs are not within desired range and beneficiary takes a 30 mcg daily dose along with calcium and vitamin D supplements, provide medical necessity for continuing the medication.
- Prescriber must submit the following:
 - Current chart notes
 - o Current labs including calcium, vitamin D, magnesium

QUANTITY EDITS:

2 pens/28 days

III. FRIENDLY REMINDERS

- 1. Any questions concerning various Medicaid topics (e.g., Medicaid enrollment, prescription coverage, provider manuals, and billing policies) may be researched using one of the following links.
 - https://humanservices.arkansas.gov/divisions-shared-services/medical-services
 - <u>https://humanservices.arkansas.gov/</u>
 - https://ar.primetherapeutics.com/

Any questions about prescription drugs or drug claims for PASSE members must be directed to the specific PASSE organization taking care of that member. For more information about PASSE, please refer to the website: <u>https://humanservices.arkansas.gov/about-dhs/dms/passe/</u>

2. For vaccine billing and updates, visit the Welcome to Arkansas webpage.

https://humanservices.arkansas.gov/

https://humanservices.arkansas.gov/covid-19/dhs-response-to-covid-19/updates-for-providers/ For adult vaccines (ages 19 and above), the following HCPCS and CPT codes are to be used in conjunction with the vaccine being administered:

G0008 - Influenza immunization

90471 - First vaccine administered

90472 – Subsequent vaccines administered

The injection administration code, **T1502**, will continue to be payable for beneficiaries of all ages. **T1502** may be used for billing the administration of subcutaneous and/or intramuscular injections only. If you have questions regarding this notice, please contact the Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at (501) 376-2211. Arkansas Medicaid provider manuals (including update transmittals), official notices, notices of rulemaking, and remittance advice (RA) messages are available for download from the Arkansas Medicaid website: <u>https://humanservices.arkansas.gov/divisions-shared-services/medical-services/</u> If assistance is needed with a Medicaid vaccine or immunization billing issue, the MMIS outreach specialists are available to help. Please refer to this website to find the outreach/provider rep for your pharmacy: <u>https://medicaid.afmc.org/services/arkansas-medicaid-management-information-system</u>

3. INCARCERATED PERSONS:

The Medicaid Pharmacy Program is prohibited by federal regulations, 42 C.F.R. §435.1009 and §435.1010, from paying for drug claims for Medicaid beneficiaries who, <u>on the date the prescription is filled</u>, is incarcerated in a correctional or holding facility, including juvenile correctional facilities, and are detained pending disposition of charges or are held under court order as material witnesses. If medications are requested for incarcerated Medicaid beneficiaries, including beneficiaries in a juvenile correctional facility, **the medications cannot be billed to Medicaid Pharmacy Program and are subject to recoupment if billed to Medicaid**. Pharmacists should contact the correctional facility regarding the facility's reimbursement procedures for the requested medications.

4. REGARDING MANUAL REVIEW PA REQUESTS:

Prior authorization (PA) requests for drugs that require a clinical manual review prior approval, require a prior authorization request for a drug as an exception to established point of sale prior approval criteria algorithm, or require a request for non-preferred drugs on the PDL, are all reviewed on a case-by-case basis through a manual review process. All manual review requests for prior authorization require, at a minimum, the prescriber to provide a letter explaining the medical necessity for the requested drug along with all written documentation to substantiate the medical necessity (e.g., chart notes, pharmacy printouts).

for cash, printout of private insurance paid drugs, lab results, etc.). Please note that starting the requested drug, <u>including long-acting injectable antipsychotic agents</u>, through either inpatient use, the use of office "samples", or by any other means, prior to a prior authorization request being reviewed and approved by the Medicaid Pharmacy Program does <u>not</u> necessitate Medicaid Pharmacy Program approval of the requested drug.

5. REGARDING EMERGENCY OVERRIDE:

In an emergency, for those drugs for which a five-day supply can be dispensed, an Arkansas Medicaid enrolled pharmacy provider may dispense up to a five-day supply of a drug that requires prior authorization (e.g., a drug that requires a clinical PA or requires a PA for a non-preferred drug). **This provision applies only** <u>in an emergency</u> when the Prime Therapeutics Help Desk and the State Medicaid Pharmacy **Program offices are closed, and the pharmacist is not able to contact the prescribing provider to change the prescription.** The Emergency Supply Policy does not apply to drugs that are not covered by the State. Frequency of the emergency override is limited to once per year per drug class for non-LTC beneficiaries and once per 60 days per drug class for LTC beneficiaries.

To submit a claim using this emergency provision, the pharmacy provider must submit "03" in the Level of Service (418-DI) field. For any Schedule-II controlled substance filled using the Medicaid Emergency Override process, please refer to the Arkansas State Board of Pharmacy regulations regarding partial fill of a Schedule-II controlled substance. See information posted on the Medicaid Pharmacy Program website, https://ar.primetherapeutics.com/provider-documents

6. HARD EDIT ON EARLY REFILL:

Non-controlled drugs:

The hard edit disallowing early refills (ER) for non-controlled drugs sooner than 75% of days' supply expended was implemented on February 16, 2016. Pharmacies will no longer be able to override the ProDUR early refill edit to refill non-controlled drugs sooner than 75% of the days' supply has elapsed. Refills for non-controlled drugs sooner than 75% of the days' supply elapsed will require a manual review PA, and the pharmacy or prescriber must provide documentation to Medicaid that the dose was increased during the month which caused the prescription to run out sooner than expected/calculated. The increased dose must be within the allowed Medicaid dose edits, or an approved PA must be in the system for the beneficiary for the higher dose or an early refill PA will not be approved.

Controlled drugs:

The hard edit disallowing early refills (ER) for controlled drugs sooner than 90% of days' supply expended was implemented January 20, 2021. This change includes opioids, CII stimulants, benzodiazepines, sedative hypnotics, etc.

7. REFILL TOO SOON ACCUMULATION LOGIC:

When a pharmacy refills a prescription claim early, the Medicaid system began adding together the accumulated "early days" filled. Each prescription is tracked by the Generic Sequence Number (GSN), which means the drug claim is the same generic name, same strength, and same dosage form, rather than tracking by prescription number or NDC.

Non-controlled drugs:

Once the beneficiary has accumulated an <u>extra</u> 12 days' supply for that GSN for non-controlled drugs, any incoming claim that is early will reject at point of sale. The accumulation edit is set so that the beneficiary cannot accumulate more than an <u>extra</u> 12 days' supply early during a 180-day period for non-controlled drugs.

Controlled drugs:

The RTS logic with Early Refill Accumulation Limit edit for controlled drugs will only allow an <u>extra</u> 7-days' supply accumulation through early fills in previous 180-day period.

8. <u>REVERSE AND CREDIT MEDICAID PRESCRIPTIONS NOT PROVIDED TO BENEFICIARY:</u>

Pharmacies are required to reverse and credit back to Medicaid original prescriptions and refills if the medication was not provided to the beneficiary. Pharmacies should reverse and credit Medicaid within 14 days of the date of service for any prescription that was not provided to the beneficiary. See the Provider Manual Update Transmittal or the Pharmacy Provider Manual Section 213.200.

9. ANTIPSYCHOTIC AGENT CRITERIA FOR CHILDREN:

< 18 YEARS OF AGE:

Each new start of any antipsychotic agent for children < 18 years of age require a completed/signed informed consent form, current metabolic labs, and documentation of medical necessity with chart notes. Beneficiaries have an ongoing requirement for labs for metabolic monitoring every 6 months. When sending for the required metabolic labs, the provider must include the PCP's name and Medicaid ID number on the lab order request form. It does not have to be the PCP ordering the labs. Please refer to the Physician/Independent Lab/CRNA/Radiation Therapy Center Provider Manual, Section II, 245.000 B.

For those providers who have not had their own version of the Informed Consent form approved for use with Medicaid PA requests and who use the Medicaid Informed Consent form for antipsychotic agents, the form may be found at the following link. <u>https://ar.primetherapeutics.com/provider-documents</u>

< 10 YEARS OF AGE:

Medicaid currently requires a manual review PA of any antipsychotic agent prescribed for children less than 10 years of age (i.e., age 9 years and under) for all new starts on an antipsychotic agent, including a change in the chemical entity for children currently on an antipsychotic agent. All documentation, chart notes, signed informed consent, and required lab work must be submitted, and the manual review will be performed by the Medicaid Pharmacy Program psychiatrist.

10. THE AR MEDICAID PHARMACY PROGRAM REIMBURSES ENROLLED PHARMACY PROVIDERS FOR COVERED OUTPATIENT DRUGS FOR MEDICAID BENEFICIARIES WITH PRESCRIPTION

DRUG BENEFITS: Only medications prescribed to that beneficiary can be billed using the beneficiary's Medicaid ID. If medications are needed to treat remaining family members, each prescription must be billed according to each family member's Medicaid ID number. Sanctions may be imposed against a provider for engaging in conduct that defrauds or abuses the Medicaid program. This could include billing a child's medication to a parent's Medicaid ID number and vice-versa.

11. ANY REIMBURSEMENT RATES STATED IN THIS MEMORANDUM (OR ANY PREVIOUS MEMORANDUMS) ARE FOR REFERENCE PURPOSES ONLY AND SUBJECT TO CHANGE:

AR Medicaid Pharmacy Program reimbursement methodology changed based on the requirements in the Affordable Care Act (ACA) and requirements of §447.502 of the final regulation and based on the CMS imposed final implementation date of April 1, 2017. The pricing methodology is lesser of methodology that applies to all brand or generic drugs for usual and customary charge, or NADAC, or ACA FUL, or SAAC. If the NADAC is not available, the allowed ingredient cost shall be WAC + 0%, SAAC, or ACA FUL. The Professional Dispensing Fee has been increased to \$9 for Brand Drugs and \$10.50 for Preferred Brand Drugs and all Generics. Reimbursement rates stated in this memo are in no way a contractual obligation by Arkansas Medicaid. NADAC pricing is subject to change and any pricing stated is only current as of the date this memo was drafted. Current Generic Upper Limits (GUL) or Maximum Allowable Cost (MAC) that have been issued at the State and or Federal level, along with State issued Capped Upper Limits (CAP), can be found on the Arkansas Medicaid website: <u>https://ar.primetherapeutics.com/provider-documents</u> A coversheet for the NADAC Help Desk Request for Medicaid Reimbursement Review form can be found on the Arkansas Medicaid website:

https://ar.primetherapeutics.com/provider-documents

12. OPIOID INFORMATION:

To provide educational materials to prescribers and pharmacists on opioid dosing, opioid use disorder, medication assisted treatment and polypharmacy, an opioid information tab has been added to the Prime Therapeutics State Government Solutions website. <u>https://ar.primetherapeutics.com/provider-documents</u>

13. HEPATITIS C TREATMENT INFORMATION:

Educational information on treating Hepatitis \overline{C} along with treatment consultations may be obtained through the Clinician Consultation Center.

- Link for the Clinician Consultation Center http://www.hepcap.org/hepatitis-c-consultation-warmline/
- 2) Hepatitis C Warmline for phone consultation—(844) HEP-INFO or (844) 437-4636

The clinical consultation staff may give advice on any of the following topics:

- HCV staging & monitoring
- Regimen selection & dosing
- Drug interactions
- HIV/HCV management strategies
- Prior HCV treatment failure, including management of complex clinical problems such as cirrhosis and renal disease
- HCV transmission & prevention
- HCV screening & diagnostic testing
- HCV in special populations (pregnancy, co-occurring substance use and/or alcohol use disorders, psychiatric disorders, post-transplant, ESRD/dialysis, pediatrics)

The Clinician Consultation Center is not affiliated with Arkansas Medicaid, but the information may be useful for providers in our state and provided only as an educational tool.

This advance notice provides you with the opportunity to contact, counsel, and change patients' prescriptions. If you need this material in an alternative format, such as large print, please contact the Program Development and Quality Assurance Unit at 501-320-6429.

If you have questions regarding this transmittal, or you need this material in an alternative format such as large print, please contact the Prime Therapeutics State Government Solutions Help Desk at 1-800-424-7895. For copies of past Remittance Advices (RA) or Arkansas Medicaid Provider Manuals (including update transmittals), please contact the Gainwell Technologies Provider Assistance Center (PAC) at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at 1-501-376-2211.