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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: May 14, 2025
- SUBJ: AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR Board April 16, 2025 meeting for the following:

Preferred Drug List Full Review: Insulins, targeted immunomodulators, and long-acting opioids

<u>Preferred Drug List Abbreviated Review</u>: Short-acting opioids, topical steroids, NSAIDs, antihyperuricemic agents, topical antifungals, antibiotic-steroid combination ophthalmic agents, glaucoma agents, allergic conjunctivitis ophthalmic agents, anti-inflammatory ophthalmic agents, and hemorrhoid preps

<u>Manual Review PA Criteria:</u> Zoryve® (roflumilast) cream (atopic dermatitis), Vtama® (tapinarof) cream (atopic dermatitis), Attruby[™] (acoramidis), Crenessity[™] (crinecerfont), Zepbound® (tirzepatide) (OSA), Sofdra[™] (sofpironium bromide), Alhemo® (concizumab-mtci), Tryngolza[™] (olezarsen), Onapgo[™] (apomorphine), Gomekli[™] (mirdametinib), Inzirqo[™] (hydrochlorothiazide), Xromi® (hydroxyurea)

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

2) CONTINUOUS GLUCOSE MONITOR UPDATE

- Abbott is discontinuing the FreeStyle Libre 2 and FreeStyle Libre 3 sensors. The FreeStyle Libre 2 and FreeStyle Libre 3 sensors will be available until September 30, 2025.
- Beneficiaries will need their healthcare provider to provide a new prescription for the FreeStyle Libre **3 Plus** or FreeStyle Libre **2 Plus** sensor.
- If the beneficiary has a FreeStyle Libre 2 reader or existing app, this can be used with FreeStyle Libre 2 Plus. If the beneficiary has a FreeStyle Libre 3 reader or existing app, this can be used with FreeStyle Libre 3 Plus.

For more information and FAQs, visit the Abbott website.

3) BLOOD GLUCOSE MONITOR UPDATE

Effective May 1, 2025, the following will be updated as a preferred option for Arkansas Medicaid.

• Freestyle Blood Glucose Meters and corresponding strips

The following Abbott blood glucose meters will be added as preferred products:

- FreeStyle Freedom Lite
- FreeStyle Lite
- FreeStyle Precision Neo
- Precision Xtra

The following Abbott blood glucose test strips will be added as preferred products:

- FreeStyle Insulinx
- FreeStyle Lite
- FreeStyle
- Precision Xtra
- FreeStyle Precision Neo

Effective May 1, 2025, the following will be updated as non-preferred options for Arkansas Medicaid.

- OneTouch Verio Reflect and corresponding test strips
- OneTouch Ultra2 and corresponding test strips
- OneTouch Verio Flex and corresponding test strips

True Metrix Meters and strips will remain as preferred diabetic supplies. Beneficiaries currently using a OneTouch product will need a new prescription for either a FreeStyle or True Metrix product beginning on May 1, 2025.

4) INFORMATIONAL DRUG UPDATES

A. <u>ALYFTREK TABLET</u>

ALYFTREK is a combination of deutivacaftor, a CFTR potentiator, tezacaftor, and vanzacaftor indicated for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one *F508del* mutation or another responsive mutation in the *CFTR* gene.

POINT-OF-SALE CRITERIA FOR OTHER CFTR AGENTS:

Criterion 1:

- Beneficiary has had a billed diagnosis of Cystic Fibrosis in the last 2 years
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for the specific requested medication
- Beneficiary is prescribed a maximum dose based on support in manufacturer's package insert

Criterion 2:

• Beneficiary Medicaid profile includes a claim for either Kalydeco®, Orkambi®, Symdeko®, or Trikafta® in the last 90 days

Beneficiaries not meeting the POS edits will require prior authorization. The prescriber must submit a prior authorization request with current chart notes documenting a Cystic Fibrosis diagnosis.

B. EVRYSDI (risdiplam)TABLET

EVRYSDI is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

EVRYSDI (risdiplam) is now available in tablet formulation in addition to a solution formulation. For the record, the tablet will require prior authorization with the same criteria as the previously Board approved criteria for the solution formulation.

C. JOURNAVX (suzetrigine) TABLET

JOURNAVX is indicated for the treatment of moderate to severe acute pain in adults.

DOSING:

- The recommended starting dose of JOURNAVX is 100 mg orally.
- Starting 12 hours after the initial dose, take 50 mg of JOURNAVX orally every 12 hours.
- Use JOURNAVX for the shortest duration, consistent with individual patient treatment goals. Use of JOURNAVX for the treatment of moderate to severe acute pain has not been studied beyond 14 days.

QUANTITY EDITS:

#30 (package size) every 60 days

5) <u>PREFERRED DRUG LIST</u> PDL UPDATE EFFECTIVE JULY 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. INSULINS

Preferred - Rapid Acting Insulin

- Insulin aspart cartridge/vial/FlexPen (generic for Novolog®)
- Insulin lispro Jr. KwikPen (generic for Humalog®)
- Insulin lispro KwikPen/vial (generic for Humalog®)

Non-Preferred - Rapid Acting Insulin

- Admelog® SoloStar pen/vial (insulin lispro)
- Afrezza® inhalation powder (insulin human)
- Apidra® SoloStar pen/vial (insulin glulisine)
- Fiasp® vial/FlexTouch Pen/Penfill/pumpcart (insulin aspart)
- Humalog® Tempo pens
- Humalog® U-100 cartridge (insulin lispro) -- BRAND ONLY
- Humalog® U-100 Jr. KwikPen (insulin lispro) -- BRAND ONLY
- Humalog® U-100 KwikPen/vial (insulin lispro) -- BRAND ONLY
- Humalog® U-200 KwikPen (insulin lispro)
- Lyumjev® U-200 KwikPen (insulin lispro-aabc)
- Lyumjev[®] KwikPen/vial (insulin lispro-aabc)
- Lyumjev[®] Tempo pen (insulin lispro-aabc)
- Novolog® U-100 cartridge/FlexPen/vial (insulin aspart)

Preferred - Rapid/Intermediate Acting Combinations

- Insulin aspart mix pen/vial (generic for Novolog® Mix)
- Insulin lispro mix pen (generic for Humalog® Mix)

Non-Preferred - Rapid/Intermediate Acting Combinations

- Humalog® Mix KwikPen (insulin lispro/lispro protamine)
- Humalog® Mix vial (insulin lispro/lispro protamine)
- Novolog® Mix FlexPen (insulin aspart/aspart protamine)
- Novolog® Mix vial (insulin aspart/aspart protamine)

Preferred - Regular Insulin

- Humulin® R U-100 vial (OTC)
- Humulin® R U-500 KwikPen/vial

Non-Preferred - Regular Insulin

• Novolin® R U-100 FlexPen/vial (OTC)

Preferred Agents – Regular/Intermediate-Acting Combinations

- Humulin® 70/30 KwikPen (OTC)
- Humulin® 70/30 vial (OTC)

Non-Preferred Agents - Regular/Intermediate-Acting Combinations

- Novolin® 70/30 vial (OTC)
- Novolin® 70/30 FlexPen (OTC)

Preferred - Intermediate Insulin

• Humulin® N U-100 vial (OTC)

Non-Preferred - Intermediate Insulin

- Humulin® N U-100 KwikPen (OTC)
- Novolin® N U-100 FlexPen (OTC)
- Novolin® N U-100 vial (OTC)

Preferred - Long Acting Insulin

- Lantus® SoloStar pen (insulin glargine)
- Lantus® vial (insulin glargine)

Non-Preferred - Long Acting Insulin

- Basaglar® KwikPen (insulin glargine)
- Basaglar® Tempo pens (insulin glargine)
- Insulin degludec U-100 and U-200 pen (generic for Tresiba®)
- Insulin degludec vial (generic for Tresiba®)
- Insulin glargine Max SoloStar pen (generic for Toujeo®)
- Insulin glargine SoloStar pen (generic for Toujeo®)
- Insulin glargine-yfgn pen/vial (generic for Semglee®)
- Levemir® FlexTouch (insulin detemir)—while product still available
- Levemir® vial (insulin detemir)—while product still available
- Rezvoglar® KwikPen (insulin glargine-aglr)
- Semglee® pen/vial (insulin glargine-yfgn)
- Soliqua® injection (insulin glargine/lixisenatide)
- Toujeo® Max SoloStar pen (insulin glargine)
- Toujeo® SoloStar pen (insulin glargine)
- Tresiba® U-100 and U-200 FlexTouch (insulin degludec)
- Tresiba® vial (insulin degludec)
- Xultophy® injection (insulin degludec/liraglutide)

2. TARGETED IMMUNOMODULATORS

Preferred Agents with Criteria

- ENBREL (etanercept) syringe/pen/cartridge/vial
- HUMIRA (adalimumab) syringe/pen
- OTEZLA (apremilast) tablet
- TALTZ (ixekizumab) syringe/autoinjector**
- XELJANZ, XELJANZ XR (tofacitinib) tablet**

**TALTZ and XELJANZ IR/XR must have trial and failure of at least ONE preferred tumor necrosis factor (TNF) blocker (i.e., Humira® or Enbrel®) unless there is a contraindication to the use of a TNF blocker.

Continuation Criteria:

- Enbrel: Look back in pharmacy claims history 45 days for 1 or more paid claims for Enbrel
- Humira: Look back in pharmacy claims history 45 days for 1 or more paid claims for Humira
- Otezla: Look back in pharmacy claims history 45 days for 1 or more paid claims for Otezla
- Taltz: Look back in pharmacy claims history 45 days for 1 or more paid claims for Taltz
- Xeljanz or Xeljanz XR: Look back in pharmacy claims history 45 days for 1 or more paid claims for Xeljanz or Xeljanz XR

Non-Preferred Agents (*Designates biosimilar)

- ABRILADA (adalimumab-afzb)* syringe/pen
- ACTEMRA (tocilizumab) syringe/autoinjector
- ADALIMUMAB-AACF (generic for Idacio)* syringe/pen
- ADALIMUMAB-AATY (generic for Yuflyma)* syringe/autoinjector
- ADALIMUMAB-ADAZ (generic for Hyrimoz)* syringe/pen
- ADALIMUMAB-ADBM (generic for Cyltezo)* syringe/pen
- ADALIMUMAB-FKJP (generic for Hulio)* syringe/pen
- ADALIMUMAB-RYVK (generic for Simlandi)* syringe/autoinjector
- AMJEVITA (adalimumab-atto)* syringe/autoinjector
- ARCALYST (rilonacept) vial
- BIMZELX (bimekizumab-bkzx) syringe/autoinjector
- CIMZIA (certolizumab) syringe
- COSENTYX (secukinumab) syringe/pen
- CYLTEZO (adalimumab-adbm)* syringe/pen
- ENSPRYNG (satralizumab-mwge) syringe
- ENTYVIO (vedolizumab) pen
- HADLIMA (adalimumab-bwwd)* syringe/autoinjector
- HULIO (adalimumab-fkjp)* syringe/pen
- HYRIMOZ (adalimumab-adaz)* syringe/pen
- IDACIO (adalimumab-aacf)* syringe/pen
- ILARIS (canakinumab) vial
- ILUMYA (tildrakizumab-asmm) syringe
- KEVZARA (sarilumab) syringe/pen
- KINERET (anakinra)
- LITFULO (ritlecitinib) capsule
- OLUMIANT (baricitinib) tablet
- OMVOH (mirikizumab-mrkz) syringe/pen
- ORENCIA (abatacept) syringe/autoinjector
- OTULFI (ustekinumab-aauz)* syringe
- PYZCHIVA (ustekinumab-ttwe)* syringe
- RINVOQ (upadacitinib) tablet/solution
- SELARSDI (ustekinumab-aekn)* syringe
- SILIQ (brodalumab) syringe
- SIMLANDI (adalimumab-ryvk)* syringe/autoinjector
- SIMPONI (golimumab) syringe/pen
- SKYRIZI (risankizumab-rzaa) syringe/on-body injector/pen
- SOTYKTU (deucravacitinib) tablet

- SPEVIGO (spesolimab-sbzo) syringe
- STELARA (ustekinumab) syringe
- STEQEYMA (ustekinumab-stba)* syringe
- TREMFYA (guselkumab) syringe/pen/autoinjector
- TYENNE (tocilizumab-aazg)* syringe/autoinjector
- VELSIPITY (etrasimod) tablet
- XELJANZ (tofacitinib) solution
- YESINTEK (ustekinumab-kfce)* syringe/45 mg vial
- YUFLYMA (adalimumab-aaty)* syringe/autoinjector
- YUSIMRY (adalimumab-aqvh)* pen
- ZYMFENTRA (infliximab-dyyb)* syringe/pen

Agents Covered Under Medical Claims Only- Please refer to AFMC for PA criteria

- ACTEMRA (tocilizumab) vial
- AVSOLA (infliximab-axxq)* vial
- COSENTYX (secukinumab) vial
- ENTYVIO (vedolizumab) vial
- INFLECTRA (infliximab-dyyb)* vial
- INFLIXIMAB (generic for Remicade®) vial
- OMVOH (mirikizumab-mrkz) vial
- ORENCIA (abatacept) vial
- OTULFI (ustekinumab-aauz)* vial
- PYZCHIVA (ustekinumab-ttwe)* vial
- REMICADE (infliximab) vial
- RENFLEXIS (infliximab-abda)* vial
- SELARSDI (ustekinumab-aekn)* vial
- SIMPONI ARIA (golimumab) vial
- SKYRIZI (risankizumab-rzaa) vial
- SPEVIGO (spesolimab-sbzo) vial
- STELARA (ustekinumab) vial
- STEQEYMA (ustekinumab-stba)* vial
- TOFIDENCE (tocilizumab-bavi)* vial
- TREMFYA (guselkumab) vial
- TYENNE (tocilizumab-aazg)* vial

3. LONG-ACTING OPIOIDS

Preferred agents with criteria

- Butrans® patch (buprenorphine) BRAND ONLY
- Morphine sulfate long-acting tablet (generic for MS Contin®)
- Tramadol ER Tablet (generic for Ultram ER®)

Non-preferred agents with criteria

- Belbuca® films (buprenorphine)
- Buprenorphine patch (generic for Butrans®)
- Fentanyl patch (generic for Duragesic®)
- Hydrocodone ER capsule (generic for Zohydro ER®)
- Hydrocodone ER tablet (generic for Hysingla ER®)
- Hydromorphone HCI extended-release tablet (generic for Exalgo ER®)
- Methadone HCI tablet (generic for Dolophine®)

- Methadone solution
- Methadone Intensol[™] conc (generic for Methadose[®])
- Morphine sulfate extended-release capsule (generic for Avinza®, Kadian®)
- Oxycodone extended-release tablet (generic for Oxycontin®)
- Oxycontin® tablet (oxycodone)
- Oxymorphone HCI extended-release tablet (generic for Opana ER®)
- Tramadol ER capsule (generic for Conzip®)
- Tramadol ER tablet (generic for Ryzolt®)

Non-preferred agents without criteria

- Conzip® capsule (tramadol ER)
- Hysingla® ER tablet (hydrocodone ER)
- Methadose® oral concentrate (methadone)
- MS Contin® tablet (morphine sulfate)

B. <u>Classes with abbreviated review</u>

4. TOPICAL ANTIFUNGALS

Preferred Topical Antifungal Agents

- Clotrimazole 1% Rx Cream
- Clotrimazole-Betamethasone Rx Cream
- Ketoconazole 2% Rx Shampoo
- Nystatin ointment, cream, powder
- Nystatin/triamcinolone ointment
- Tolnaftate 1% topical cream OTC
- Tolnaftate 1% topical powder OTC
- Tolnaftate 1% topical solution OTC

Non-Preferred Topical Antifungal Agents

- Ciclodan® 0.77%, kit cream (ciclopirox)
- Ciclopirox 0.77% cream, gel, topical suspension (generic for Loprox®)
- Ciclopirox 1% shampoo (generic for Loprox®)
- Clotrimazole 1% Rx solution
- Clotrimazole-Betamethasone Rx lotion
- Econazole 1% cream
- Ertaczo[®] 2% cream (sertaconazole)
- Extina® 2% foam (ketoconazole)
- Ketoconazole 2% cream (generic for Nizoral®)
- Ketoconazole 2% foam (generic for Extina®)
- Klayesta® powder (nystatin)
- Loprox® 0.77% cream, topical suspension (ciclopirox)
- Luliconazole cream 1% (generic for Luzu®)
- Luzu® 1% cream (luliconazole)
- Miconazole 0.25%/zinc oxide 15%/white petrolatum ointment 81.35% (generic for Vusion®)
- Naftifine 1%, 2% cream and 2% gel (generic for Naftin®)
- Nystatin/triamcinolone cream
- Oxiconazole 1% cream (generic for Oxistat®)
- Oxistat 1% lotion (oxiconazole)
- Vusion® ointment (miconazole/zinc oxide/white petroleum)

Non-Preferred Topical Antifungal Agents for Onychomycosis

- Ciclodan 8% topical nail solution (ciclopirox)
- Ciclopirox 8% topical nail solution (generic for Penlac® Nail Lacquer)
- Jublia® 10% topical nail solution (efinaconazole)
- Tavaborole 5% topical nail solution (generic for Kerydin®)

5. ANTI-HYPERURICEMICS

Preferred Agents

- Allopurinol 100 mg, 300 mg tablet (generic for Zyloprim®)
- Colchicine tablet (generic for Colcrys®)
- Probenecid tablet
- Probenecid/colchicine tablet

Non-preferred Agents

- Allopurinol 200 mg tablet (generic for Zyloprim®)
- Colchicine capsule (generic for Mitigare®)
- Colcrys® tablet (colchicine)
- Febuxostat tablet (generic for Uloric®)
- Gloperba solution (colchicine)
- Mitigare® capsule (colchicine)
- Uloric® tablet (febuxostat)
- Zyloprim® tablet (allopurinol)

6. ANTI-INFLAMMATORY AGENTS (NSAIDs)

Preferred agents

- Celecoxib capsule (generic for Celebrex®)
- Diclofenac sodium 25mg, 50mg, and 75 mg tablet (generic for Voltaren®)
- Diclofenac sodium topical 1% gel (generic for Voltaren®)
- Ibuprofen 100 mg/5 ml suspension (generic for Motrin®)
- Ibuprofen 400 mg, 600 mg, 800 mg tablets (generic for Motrin®)
- Indomethacin 25 mg, 50 mg, capsule (generic for Indocin®)
- Meloxicam 7.5 mg and 15 mg tablets (generic for Mobic®)
- Nabumetone tablet (generic for Relafen®)
- Naproxen 250 mg, 375 mg, 500 mg tablets (generic for Naprosyn)
- Naproxen 375 mg, 500 mg, Enteric coated tablets (generic for EC-Naprosyn®)
- Naproxen 275 mg, 550 mg tablets (generic for Anaprox®)

Preferred agent with criteria

• Ketorolac tablet (generic for Toradol®)

Nonpreferred agents

- Arthrotec® tablet (diclofenac sodium/misoprostol)
- Celebrex® capsule (celecoxib)
- Daypro® tablet (oxaprozin)
- Diclofenac epolamine 1.3% patch (generic for Flector®)
- Diclofenac potassium tablet (generic for Cataflam®)
- Diclofenac potassium capsule (generic for Zipsor®)
- Diclofenac sodium ER tablet (generic for Voltaren XR)
- Diclofenac sodium topical 1.5%, 2% (generic for Pennsaid®)

- Diclofenac sodium/Misoprostol (generic for Arthrotec®)
- Diflunisal tablet (generic for Dolobid®)
- Dolobid tablet (diflunisal)
- Etodolac tablet and capsule (generic for Lodine®)
- Etodolac ER tablet (generic for Lodine XL®)
- Feldene capsule (piroxicam)
- Fenoprofen tablet and capsule (generic for Nalfon®)
- Fenopron® capsule (fenoprofen calcium)
- Flurbiprofen tablet (generic for Ansaid®)
- Ibuprofen/famotidine tablet (generic for Duexis®)
- Indomethacin 25mg/5ml suspension (generic for Indocin®)
- Indomethacin 75mg SA capsule (generic for Indocin®)
- Indomethacin 50 mg suppository (generic for Indocin[®])
- Ketoprofen 200mg extended-release capsule (generic for Oruvail®)
- Ketoprofen capsules (generic for Orudis®)
- Meclofenamate sodium capsule (generic for Meclomen®)
- Mefenamic acid capsule (generic for Ponstel®)
- Meloxicam capsule (generic for Vivlodex®)
- Nalfon® tablet and capsule (fenoprofen calcium)
- Naprelan® CR tablet (naproxen)
- Naproxen sodium 375 mg, 500 mg, 750 mg ER/CR tablet (generic for Naprelan®)
- Naproxen/Esomeprazole magnesium tablet (generic for Vimovo®)
- Oxaprozin tablet (generic for Daypro®)
- Pennsaid 2% topical solution (diclofenac sodium)
- Piroxicam capsule (generic for Feldene®)
- Relafen® DS tablet (nabumetone)
- Salsalate tablet (generic for Disalcid®)
- Sulindac tablet (generic for Clinoril®)
- Tolectin® tablet (tolmetin)
- Tolmetin sodium capsule (generic for Tolectin® DS)
- Tolmetin sodium tablet (generic for Tolectin® 600)

Nonpreferred agents with criteria

- Diclofenac Sodium 3% Gel (Solaraze®)*
- Naproxen suspension (generic for Naprosyn®)

*Diclofenac Sodium 3% gel requires a billed diagnosis of Actinic Keratosis in the past two months to process at Point-of-Sale without prior authorization.

7. TOPICAL CORTICOSTEROIDS

Potency Class 1 – Superpotent, Preferred Status only for package sizes noted:

- Clobetasol propionate 0.05% solution 25 ml, 50ml
- Clobetasol propionate 0.05% cream, 15 gm, 30 gm, 45 gm, 60 gm
- Clobetasol propionate 0.05% cream-emollient, 15 gm, 30 gm, 60 gm
- Clobetasol propionate 0.05% ointment, 15 gm, 30 gm, 45 gm, 60 gm
- Fluocinonide 0.1% cream, 30 gm, 60 gm, 120 gm
- Halobetasol propionate 0.05% cream, 15 gm, 50 gm

Potency Class 1 – Superpotent, Non-Preferred, for all package sizes unless otherwise noted:

- Betamethasone dipropionate augmented 0.05% gel
- Betamethasone dipropionate augmented 0.05% lotion
- Betamethasone dipropionate augmented 0.05% ointment (generic for Diprolene®)
- Bryhali® 0.1% lotion (halobetasol propionate)
- Clobetasol propionate 0.05% emollient foam
- Clobetasol propionate 0.05% foam
- Clobetasol propionate 0.05% gel
- Clobetasol propionate 0.05% lotion
- Clobetasol propionate 0.05% shampoo and spray (generic for Clobex®)
- Clobex® 0.05% shampoo and spray (clobetasol propionate)
- Clodan® 0.05% shampoo (clobetasol propionate)
- Desoximetasone 0.25% spray
- Diflorasone diacetate 0.05% ointment
- Diprolene® 0.05% ointment (betamethasone dipropionate augmented)
- Halobetasol propionate 0.05% foam (generic for Lexette®)
- Halobetasol propionate 0.05% ointment, 15 gm, 50 gm
- Tovet 0.05% emollient foam (clobetasol propionate)
- Ultravate 0.05% lotion (halobetasol propionate)
- Vanos® 0.1% cream (fluocinonide)

Potency Class 2 – Potent, Preferred Status only for package sizes noted:

- Betamethasone dipropionate augmented 0.05% cream, 15 gm, 50 gm
- Fluocinonide 0.05% cream, 15 gm, 30 gm, 60 gm, 120 gm
- Fluocinonide 0.05% ointment, 15 gm, 30 gm, 60 gm
- Triamcinolone 0.5% ointment, 15 gm

Potency Class 2– Potent, Non-Preferred, for all package sizes unless otherwise noted:

- Apexicon E 0.05% cream (diflorasone diacetate)
- Clobetasol propionate 0.025% cream
- Desoximetasone 0.25% cream
- Desoximetasone 0.05% gel
- Desoximetasone 0.25% ointment
- Diflorasone 0.05% cream
- Fluocinonide 0.05% gel
- Fluocinonide 0.05% solution
- Halcinonide 0.1% cream
- Halcinonide 0.1% solution
- Topicort 0.25% cream (desoximetasone)
- Topicort 0.05% gel (desoximetasone)

Potency Class 3 – Upper-Mid Strength, Preferred Status only for package sizes noted:

- Betamethasone dipropionate 0.05% (not augmented) lotion, 60 ml
- Betamethasone valerate 0.1% ointment, 15 gm, 45 gm
- Mometasone furoate 0.1% ointment, 15 gm, 45 gm
- Triamcinolone 0.5% cream, 15 gm
- Triamcinolone 0.1% ointment 15 gm, 30 gm, 80 gm

Potency Class 3 – Upper-Mid Strength, Non-Preferred, for all package sizes unless otherwise noted:

- Amcinonide 0.1% cream
- Betamethasone dipropionate 0.05% cream (not augmented)
- Betamethasone dipropionate 0.05% ointment (not augmented)
- Betamethasone valerate 0.12% foam
- Fluocinonide 0.05% emollient cream
- Fluticasone propionate 0.005% ointment
- Triamcinolone 0.1% ointment 454 gm and 453.6 gm

Potency Class 4 – Mid Strength, Preferred Status only for package sizes noted:

- Fluocinolone 0.025% ointment, 15 gm, 60 gm
- Mometasone furoate 0.1% cream, 15 gm, 45 gm
- Mometasone furoate 0.1% solution or lotion, 30 ml, 60 ml
- Triamcinolone 0.1% cream, 15 gm, 30 gm, 80 gm

Potency Class 4 – Mid Strength, Non-Preferred, for all package sizes unless otherwise noted:

- Clocortolone pivalate 0.1% cream
- Desoximetasone 0.05% cream
- Desoximetasone 0.05% ointment
- Flurandrenolide 0.05% ointment
- Hydrocortisone valerate 0.2% ointment
- Synalar 0.025% ointment (fluocinolone)
- Triamcinolone 0.1% cream, 454 gm and 453.6 gm
- Triamcinolone acetonide 0.1% aerosol spray

Potency Class 5 – Lower-Mid Strength, Preferred Status only for package sizes noted:

- Betamethasone valerate 0.1% cream, 15 gm, 45 gm
- Fluocinolone 0.01% cream, 15 gm, 60 gm
- Fluocinolone 0.025% cream, 15 gm, 60 gm
- Fluticasone propionate 0.05% cream, 15 gm, 30 gm, 60 gm
- Triamcinolone 0.025% lotion, 60 ml
- Triamcinolone 0.025% ointment 15 gm, 80 gm
- Triamcinolone 0.1% lotion, 60 ml

Potency Class 5 – Lower-Mid Strength, Non-Preferred, for all package sizes unless otherwise noted:

- Beser 0.05% lotion (fluticasone)
- Betamethasone valerate 0.1% lotion
- Capex shampoo (fluocinolone)
- Desonide 0.05% lotion
- Desonide 0.05% ointment
- Flurandrenolide 0.05% lotion
- Fluticasone propionate 0.05% lotion
- Hydrocortisone butyrate 0.1% cream
- Hydrocortisone butyrate 0.1% lotion
- Hydrocortisone butyrate 0.1% ointment
- Hydrocortisone butyrate 0.1% solution
- Hydrocortisone valerate 0.2% cream

- Locoid lipocream 0.1% (hydrocortisone butyrate emollient)
- Prednicarbate 0.1% cream emollient
- Prednicarbate 0.1% ointment
- Synalar 0.025% cream (fluocinolone)
- Triamcinolone 0.025% ointment, 454 gm, 430 gm
- Triamcinolone 0.05% ointment, 430 gm

Potency Class 6 – Mild, Preferred Status only for package sizes noted:

- Desonide 0.05% cream, 15gm, 60gm
- Fluocinolone 0.01% solution, 60 ml
- Triamcinolone 0.025% cream, 15 gm, 80 gm

Potency Class 6 – Mild, Non-Preferred, for all package sizes unless otherwise noted:

- Alclometasone dipropionate 0.05% cream
- Alclometasone dipropionate 0.05% ointment
- Derma-Smooth FS 0.01% body/scalp oil (fluocinolone)
- Fluocinolone 0.01% scalp/body oil
- Synalar 0.1% solution (fluocinolone)
- Triamcinolone 0.025% cream, 454 gm

Potency Class 7 – Least Potent, Preferred Status only for package sizes noted:

- Hydrocortisone acetate 0.5% cream (covered OTC), 28.4 gm
- Hydrocortisone 0.5% cream (covered OTC), 28.4 gm, 28.35 gm
- Hydrocortisone 1% cream, 28.35 gm, 28.4 gm
- Hydrocortisone 1% ointment, 28.35gm, 28.4 gm
- Hydrocortisone 2.5% cream, 20 gm, 28 gm, 28.35 gm, 30 gm
- Hydrocortisone 2.5% ointment, 20 gm, 28.35 gm, 28.4 gm

Potency Class 7 – Least Potent, Non-Preferred, for all package sizes unless otherwise noted:

- Hydrocortisone 1% cream, 453.6 gm, 454 gm
- Hydrocortisone 1% ointment, 453.6 gm
- Hydrocortisone 2.5% cream 453.6 gm
- Hydrocortisone 2.5% ointment, 453.6 gm, 454 gm
- Hydrocortisone 2.5% lotion
- Hydrocortisone 2.5% solution
- Texacort 2.5% solution (hydrocortisone)

The quantity limit for topical corticosteroids, in general, for each topical corticosteroid agent will be limited to one package size for the NDC (e.g., one 15 gm tube, one 30 gm tube, etc.), up to a 240 gm package size if the agent is available in a 240 gm size. Topical solutions and lotions will be limited to the smaller package size available for that drug entity.

8. GLAUCOMA AGENTS

Preferred Status only for strengths and package sizes noted:

- Alphagan P® 0.15% drops 5 ml, 10 ml, 15 ml (brimonidine)-BRAND ONLY
- Carteolol 1% solution drops 5 ml, 10 ml, 15 ml (generic for Ocupress®)
- Combigan® solution drops 5 ml, 10 ml, 15 ml (brimonidine/timolol)-BRAND ONLY
- Dorzolamide 2% drops 10 ml (generic for Trusopt®)
- Dorzolamide/timolol 22.3- 6.8 mg/ml drops 10 ml (generic for Cosopt®)
- Latanoprost 0.005% solution drops 2.5 ml (generic for Xalatan®)
- Levobunolol 0.5% solution drops 5 ml (generic for Betagan®)
- Lumigan® 0.01% solution drops 2.5ml, 5ml (bimatoprost)
- Rhopressa® 0.02% drops 2.5 ml (netarsudil)
- Rocklatan® 0.02%/0.005% drops 2.5 ml (netarsudil/latanoprost)
- Timolol 0.25%, 0.5% solution drops 5 ml, 10 ml, 15 ml (generic for Timoptic®)

Non-Preferred Status, all package sizes unless otherwise noted:

- Alphagan P® 0.1% drops (brimonidine)
- Apraclonidine 0.5% solution drops (generic for lopidine®)
- Azopt® 1% suspension drops (brinzolamide)
- Betaxolol 0.5% solution drops (generic for Betoptic®)
- Betimol® 0.25% and 0.5% drops (timolol)
- Betoptic S® 0.25% drops (betaxolol)
- Bimatoprost 0.03% solution drops (generic for Lumigan®)
- Brimonidine 0.1%, 0.15% 0.2% drops (generic for Alphagan®/Alphagan P®)
- Brimonidine 0.2%/ timolol 0.5% drops (generic for Combigan®)
- Brinzolamide 1% suspension drops (generic for Azopt®)
- Cosopt® 2%/0.5% drops (dorzolamide/timolol)
- Cosopt® PF 2%/0.5% drops (dorzolamide/timolol)
- Dorzolamide 2% /timolol 0.5% solution drops (generic for Cosopt® PF)
- Istalol® 0.5% drops (timolol maleate)
- lyuzeh® 0.005% drops (latanoprost)
- Phospholine lodide 0.125% kit (echothiophate)
- Pilocarpine 1%, 2%, 4% solution drops (generic for Pilocar®)
- Simbrinza® suspension drops (Brimonidine 1%/ brinzolamide 0.2%)
- Tafluprost 0.0015% drops (generic for Zioptan®)
- Timolol 0.25%, 0.5% gel forming solution (generic for Timoptic-XE®)
- Timolol 0.5% drops (generic for Betimol®)
- Timolol maleate 0.5% drops (generic for Istalol®)
- Timolol preservative free 0.25%, 0.5% (generic for Timoptic Ocudose®)
- Timoptic Ocudose 0.25%, 0.5% (timolol)
- Travoprost 0.004% drops (generic for Travatan Z®)
- Vyzulta® 0.024% drops (latanoprostene bunod)
- Xalatan® 0.005% drops (latanoprost)
- Xelpros® 0.005% solution/drops (latanoprost)
- Zioptan® 0.0015% drops (tafluprost)

9. <u>HEMORRHOID PREPARATIONS</u> Preferred Drugs:

- Hydrocortisone 1% cream
- Hydrocortisone 2.5% cream
- Hydrocortisone- Pramoxine 1%-1% cream
- Proctofoam-HC 1-1% (hydrocortisone-pramoxine)
- Procto-Med HC 2.5% cream (hydrocortisone)
- Procto-Sol HC 2.5% cream (hydrocortisone)

Non-Preferred Drugs:

- Anu-Sol HC 2.5% cream (hydrocortisone)
- Cortifoam 10% foam (hydrocortisone)
- Proctozone-HC 2.5% cream (hydrocortisone)

10. OPHTHALMICS - ALLERGIC CONJUNCTIVITIS

Preferred agents

- Azelastine HCI 0.05% eye drops (generic for Optivar®)
- Cromolyn sodium 4% eye drops (generic for Opticrom®)
- Ketotifen fumarate 0.025% eye drops (generic for Alaway® or Zaditor®)
- Olopatadine HCI 0.1% eye drops (generic for Patanol®)
- Olopatadine HCI 0.2% eye drops (generic for Pataday®)

Non-Preferred agents

- Alrex® 0.2% eye drops (loteprednol)
- Bepotastine besilate 1.5% eye drops (generic for Bepreve®)
- Bepreve® 1.5% eye drops (bepotastine besilate)
- Epinastine HCI 0.05% eye drops (generic for Elestat®)
- Loteprednol etabonate 0.2% eye drops (generic for Alrex®)
- Pataday® 0.7% eye drops (olopatadine)
- Zerviate® 0.24% eye drop (cetirizine)
- Zaditor 0.025% eye drops (ketotifen fumarate)

11. OPHTHALMICS - ANTIBIOTIC-STEROID COMBOS

Preferred Status:

- Neomycin sulfate/polymyxin B/dexamethasone 0.1% eye suspension drops (generic for Maxitrol®)
- Neomycin sulfate/polymyxin B/dexamethasone eye ointment (generic for Maxitrol®)
- Sulfacetamide sodium 10% / prednisolone sodium phosphate 0.23% eye solution drops
- Tobradex® eye ointment (tobramycin 0.3% / dexamethasone 0.1%)
- Tobramycin 0.3%/dexamethasone 0.1% eye suspension drops (generic for Tobradex®)

Non-Preferred Status:

- Maxitrol® (neomycin/polymyxin B/dexamethasone) eye suspension drops
- Maxitrol® eye ointment (neomycin/polymyxin B/dexamethasone)
- Neomycin 3.5 mg/ polymyxin B sulfates 10K / hydrocortisone 1% eye suspension drops (generic for Cortisporin®)
- Neomycin sulfate/ polymyxin B sulfates/ bacitracin zinc/ hydrocortisone eye ointment (generic for Cortisporin®)
- Tobradex® ST eye suspension drops (tobramycin 0.3% / dexamethasone 0.05%)
- Zylet® eye suspension drops (loteprednol 0.5%/tobramycin 0.3%)

12. OPHTHALMICS - ANTI-INFLAMMATORY

Preferred agents

- Bromfenac 0.09% eye drops (generic for Bromday®)
- Dexamethasone Sodium Phosphate 0.1% eye drops (generic for Decadron®)
- Diclofenac 0.1% eye drops (generic for Voltaren®)
- Fluorometholone 0.1% eye suspension drops (generic for FML Liquifilm®)
- Flurbiprofen 0.03% eye drops (generic for Ocufen®)
- FML Forte® 0.25% eye suspension drops (fluorometholone)
- Ketorolac 0.5% eye drops (generic for Acular®)
- Prednisolone acetate 1% eye suspension drops (generic Pred Forte®)
- Prednisolone sodium 1% eye drops (generic for AK-Pred®)

Non- Preferred agents

- Acular® 0.5%, Acular LS® 0.4% eye drops (ketorolac)
- Acuvail® 0.45% eye drops (ketorolac)
- Bromfenac 0.07% eye drops (generic for Prolensa®)
- Bromfenac 0.075% eye drops (generic for BromSite®)
- BromSite® 0.075% eye drops (bromfenac)
- Difluprednate 0.05% eye drops (generic for Durezol®)
- Durezol® 0.05% eye drops (difluprednate)
- Eysuvis® 0.25% eye suspension drops (loteprednol)
- Flarex® 0.1% eye suspension drops (fluorometholone)
- FML Liquifilm® 0.1% eye suspension drops (fluorometholone)
- Ilevro® 0.3% eye suspension drops (nepafenac)
- Inveltys® 1% eye suspension drops (loteprednol)
- Ketorolac 0.4% eye drops (generic for Acular LS®)
- Lotemax SM® 0.38% eye gel drops (loteprednol etabonate)
- Lotemax® 0.5% eye drops/12ps (loteprednol)
- Lotemax® 0.5% eye gel drops (loteprednol)
- Lotemax® 0.5% eye ointment (loteprednol)
- Loteprednol etabonate 0.5% eye drops/12ps (generic for Lotemax®)
- Loteprednol etabonate 0.5% eye gel drops (generic for Lotemax®)
- Maxidex® 0.1% eye suspension drops (dexamethasone)
- Nevanac®) 0.1% eye suspension drops (nepafenac)
- Pred Forte® 1% eye suspension drops (prednisolone)
- Pred Mild® 0.12% eye suspension drops (prednisolone)
- Prolensa® 0.07% eye drops (bromfenac)

13. SHORT-ACTING OPIOIDS

Preferred Status only for strengths noted: (Quantity edits, MME edits, accumulation edits, and refill too soon edits apply)

- Acetaminophen-codeine 120 mg-12 mg/5 mL oral solution 473 ml bottle
- Acetaminophen-codeine 300-15 mg, 300-30 mg, 300-60 mg tablet
- Codeine 15 mg, 30 mg, 60 mg tablet
- Hydrocodone/ acetaminophen 7.5-325 mg/15 mL oral solution
- Hydrocodone/ acetaminophen 5/325 mg, 7.5/325 mg, 10/325 mg tablet (generic for Norco®)
- Hydrocodone/ibuprofen 7.5/200 mg tablet (generic for Vicoprofen®)
- Hydromorphone tablet 2 mg, 4 mg, 8 mg tablet (generic for Dilaudid®)

- Meperidine 50 mg/ 5 mL oral solution (generic for Demerol®)
- Meperidine 50 mg tablet (generic for Demerol®)
- Morphine concentrated 100 mg/5 mL oral solution
- Morphine IR 15 mg, 30 mg tablet (generic for MSIR)
- Morphine 10 mg/5 mL, 20 mg/5 mL oral solution
- Oxycodone 5 mg/ 5 ml oral solution (generic for Roxicodone®)
- Oxycodone 5 mg, 10 mg, 15 mg, 20 mg, 30 mg tablet (generic for Roxicodone®)
- Oxycodone/ acetaminophen 5-325 mg/ 5 ml oral solution (generic for Roxicet®)
- Oxycodone/ acetaminophen 5 mg-325 mg, 7.5 mg-325mg, 10mg–325 mg tablet (generic for Percocet®)
- Tramadol tablet 50 mg (generic for Ultram®)
- Tramadol/ acetaminophen 37.5 mg-325 mg tablet (generic for Ultracet®)

Non-Preferred Status for all strengths unless otherwise noted

- Acetaminophen-codeine 120 mg-12 mg/5 mL and 300 mg-30 mg/12.5 mL oral solution (unit dose cups)
- Butalbital/caffeine/APAP w/codeine 50 mg-40 mg-325 mg-30 mg and 50 mg-40 mg-300 mg-30mg capsules (generic for Fioricet® with Codeine)
- Butalbital/caffeine/ASA w/codeine 50 mg-40 mg-325 mg-30 mg capsules (generic for Fiorinal® with Codeine)
- Butorphanol 10 mg/ml nasal spray (generic for Stadol® NS)
- Carisoprodol/ASA w/Codeine tablet (generic for Soma Compound with Codeine)
- Dilaudid® tablet and oral solution (hydromorphone)
- Fioricet® with Codeine 50 mg-40 mg-300 mg-30mg capsules (butalbital/caffeine/APAP w/codeine)
- Hydrocodone/APAP 10 mg-325 mg/15 ml oral solution (generic for Zamicet®)
- Hydrocodone/APAP 7.5-325 mg/15 ml, 2.5-108 mg/ 5 ml, 5-217 mg/ 10 ml oral solution (unit dose cups)
- Hydrocodone/APAP 5-300 mg, 7.5-300 mg, 10-300 mg, 2.5-325 mg tablet
- Hydrocodone-ibuprofen 10 mg-200 mg, 5 mg-200 mg tablet (generic for Ibudone® and Reprexain[™])
- Hydromorphone 1 mg/1 ml oral solution (generic for Dilaudid®)
- Levorphanol 2 mg tablets
- Oxycodone 5 mg/5 ml oral solution (unit dose cups)
- Oxycodone 5 mg capsule (generic for OXYIR)
- Oxycodone concentrated 20 mg/ml oral solution (generic for Roxicodone Intensol®)
- Oxycodone/ APAP 2.5 mg-325 mg tablet (generic for Percocet®)
- Oxymorphone tablets (generic for Opana®)
- Pentazocine/naloxone tablet (generic for Talwin NX®)
- Percocet tablet (oxycodone/APAP)
- Prolate® 5 mg-300 mg, 7.5 mg-300 mg, 10 mg-300mg,10-300mg/5ml (Oxycodone/APAP)
- Roxicodone® tablet (oxycodone)
- Roxybond 5 mg, 10 mg, 15 mg, 30 mg tablet (oxycodone)
- Tramadol 25 mg, 75 mg, 100 mg tablets
- Tramadol 5 mg/ml oral solution (generic for Qdolo®)

II. PRIOR AUTHORIZATION DRUG CRITERIA (NEW OR REVISED): CRITERIA EFFECTIVE APRIL 16, 2025

1. ZORYVE (roflumilast) CREAM & VTAMA (tapinarof) CREAM

APPROVAL CRITERIA FOR ATOPIC DERMATITIS FOR ZORYVE:

- Beneficiary must be ≥6 years of age
- Beneficiary should have mild or moderate atopic dermatitis defined by an Investigator's Global Assessment (IGA) score of 2-3 out of a 0-4 scale
- Beneficiary must have uncontrolled mild to moderate atopic dermatitis with recent claims for topical corticosteroids and topical calcineurin inhibitors (TCI)
 - Trials of at least two different topical corticosteroid entities over a minimum of 60 days use with at least one topical corticosteroid being "high" potency (Class-2) or super potent (Class-1) depending on location of atopic dermatitis
 - At least one trial of a TCI over a minimum of 30 days (i.e., tacrolimus, pimecrolimus)
- Prescriber must submit the following:
 - o Current chart notes
 - Documentation of previous therapies
 - o Current IGA score
 - Current baseline Itch Numerical Rating Scale (Itch NRS)
- If approved, PA will be approved for 2 months

APPROVAL CRITERIA FOR ATOPIC DERMATITIS FOR VTAMA:

- Beneficiary must be ≥2 years of age
- Beneficiary should have moderate to severe atopic dermatitis defined by an Investigator's Global Assessment (IGA) score of 3-4 out of a 0-4 scale
- Beneficiary must have uncontrolled moderate to severe atopic dermatitis with recent claims for topical corticosteroids and topical calcineurin inhibitors (TCI)
 - Trials of at least two different topical corticosteroid entities over a minimum of 60 days use with at least one topical corticosteroid being "high" potency (Class-2) or super potent (Class-1) depending on location of atopic dermatitis
 - At least one trial of a TCI over a minimum of 30 days (i.e., tacrolimus, pimecrolimus)
- Prescriber must submit the following:
 - Current chart notes
 - Documentation of previous therapies
 - o Current IGA score
 - Current baseline Itch Numerical Rating Scale (Itch NRS)
 - If approved, PA will be approved for 2 months

IMMUNOMODULATORS ATOPIC DERMATITIS (topical and biologics)

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

Preferred Agent

• 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)

- Cibinqo®* tablet (abrocitinib)
- Elidel® cream (pimecrolimus)
- Eucrisa® ointment (crisaborole)
- Nemluvio®* injection (nemolizumab-ilto)
- Opzelura®* cream (ruxolitinib)
- Pimecrolimus cream (generic for Elidel®)
- Protopic® ointment (tacrolimus)
- Rinvoq®* tablet (upadacitinib)
- Vtama®* cream (tapinarof)
- Zoryve®* 0.15% cream (roflumilast)

2. ATTRUBY (acoramidis hcl) 356 mg tablet

ATTRUBY is indicated for the treatment of the cardiomyopathy of wild-type or variant transthyretinmediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization.

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
 manufacturar's package insert or based on support from the efficiel Compandia
- manufacturer's package insert or based on support from the official Compendia
 Beneficiary must have the diagnosis of cardiomyopathy of wild-type or variant transthyretinmediated amyloidosis (ATTR-CM) confirmed with **TWO** of the following:
 - Echocardiogram; OR
 - Tissue biopsy confirming the presence of transthyretin amyloid deposits; **OR**
 - Cardiovascular magnetic resonance imaging
 - If consistent with cardiac amyloidosis, the following should be done to document the presence or absence of monoclonal protein confirmed by <u>ALL</u> of the following:
 - Serum kappa/lambda free light chain ratio analysis
 - Serum protein immunofixation
 - Urine protein immunofixation
 - If monoclonal protein is not found, bone tracer cardiac scintigraphy (pyrophosphate scan) should be performed. Presence of grade 2 or 3 is highly specific for ATTR cardiac disease and tissue biopsy is not needed, but genetic testing is needed to confirm TTR variant.
- Must be prescribed by, or in consultation with, a cardiologist
- Beneficiary must have New York Heart Association Class (NYHA) I, II, or III heart failure with symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema)
- Beneficiary must have left ventricular wall (interventricular septum or left ventricular posterior wall) thickness ≥ 12 mm
- Beneficiary should not be approved or continue the medication if meets one of the following:
 - Impaired renal function (eGFR < 15 mL/min/1.73m²)
 - Baseline NT-proBNP <300 pg/mL or ≥8500 pg/mL
 - Goal of treatment is strictly polyneuropathy
 - Prescriber must submit the following:
 - Current chart notes
 - Symptoms specific to this patient to support diagnosis
 - Baseline 6-minute walk distance (6MWD)
 - Current labs including baseline eGFR and NT-proBNP level (≥ 300 pg/mL)
 - Baseline echocardiogram with NYHA classification and documentation of tests results to confirm diagnosis
 - Baseline Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS) score

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to treatment
- Prescriber must submit the following:
 - Current chart notes
 - o Documentation of patient specific symptoms compared to baseline
 - Updated 6-minute walk distance (6MWD)
 - Current Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS) score

QUANTITY EDITS:

#120/30 days

3. CRENESSITY (crinecerfont) 25 mg, 50 mg, & 100 mg capsule and 50 mg/mL oral solution

CRENESSITY is a corticotropin-releasing factor type 1 receptor antagonist indicated as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH).

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 diagnosed with classic congenital adrenal hyperplasia with 21-hydroxylase deficiency and meets <u>ONE</u> of the following:
 - Requires supraphysiological glucocorticoid doses and has normal androgen levels; OR
 - Glucocorticoids provide inadequate androgen control
- Prescribed by, or in consultation with, an endocrinologist
- Beneficiary must remain on glucocorticoid replacement therapy
- Beneficiary requiring concomitant moderate or strong CYP3A4 inducer (e.g., carbamazepine, phenobarbital, bosentan, modafinil) will need dose modification
- Beneficiary should not be approved or continue the medication if meets one of the following:
 - Has severe renal impairment or end-stage renal disease
 - Is not prescribed concomitant glucocorticoids
- Prescriber must submit the following:
 - Current chart notes with documentation to support the diagnosis
 - Previous therapies tried with doses
 - Current glucocorticoid dose
 - o Current serum androgen levels
 - Current comprehensive lab panel
 - Current weight to confirm proper dosing
- Initial prior authorization will be for 3 months, subsequent approvals may be up to 6 months

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to treatment with a decrease in required glucocorticoid daily doses compared to baseline and decrease in androgen levels (if elevated at baseline)
- Prescriber must submit the following:
 - Current chart notes
 - Current glucocorticoid dose
 - Current serum androgen levels

QUANTITY EDITS:

- #60/30 days for each capsule strength (PA override for exceeding this quantity if requires a CYP3A4 inducer)
- #120 ml/30 days for oral solution (PA override for exceeding this quantity if requires a CYP3A4 inducer)

4. ZEPBOUND (tirzepatide) 10 mg and 15 mg injection—OSA indication only

ZEPBOUND is indicated in combination with a reduced-calorie diet and increased physical activity:

- to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition.
- to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

Arkansas Medicaid does not cover medications solely for weight loss. The criteria listed below pertain to the obstructive sleep apnea indication only.

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 diagnosed with moderate to severe obstructive sleep apnea (OSA) defined as apnea-hypopnea index (AHI) ≥15 respiratory events per hour based on polysomnography (PSG) results.
- Beneficiary must have a baseline diagnosis of obesity defined as body mass index (BMI) ≥ 30 kg/m² AND at least <u>ONE</u> of the following weight-related comorbid conditions:
 - Cardiovascular disease; OR
 - Type II diabetes mellitus; **OR**
 - Dyslipidemia; **OR**
 - Hypertension
- Medication must be prescribed by, or in consultation with, a neurologist, pulmonologist, otolaryngologist, or other sleep medicine specialist. PA requests are not required from a specialist, but the specialist should have performed the sleep study and provided a report.
- Beneficiary must have been participating in a comprehensive weight management program for at least 6 months with documented counseling on behavioral modification, reduced-calorie diet, and increased physical activity.
- Beneficiary should not be approved or continue the medication if meets one of the following:
 - Has not been on a weight management program for at least 6 months
 - Has not been compliant with nightly CPAP use
 - Prescribed another tirzepatide-containing product or any glucagon-like peptide 1 (GLP-1) receptor agonist to be used concurrently
 - Personal or family history of medullary thyroid carcinoma (MTC)
 - Diagnosed with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
 - Requested for weight loss only
 - Has been diagnosed with severe gastrointestinal disease including gastroparesis
 - Has a history of pancreatitis
 - Has a history of suicidal attempts or active suicidal ideation
- Beneficiary must have at least a 6-month history of compliant positive airway pressure (CPAP or BiPAP) use without a decrease in AHI below 15 events per hour.
- Prescriber must submit the following:
 - o Current chart notes
 - Most recent polysomnography (PSG) results including AHI after CPAP or BiPAP trial
 - Patient specific symptoms attributable to OSA (e.g., self-reported daytime sleepiness, snoring episodes, and AHI events)
 - CPAP/BiPAP usage report
 - Current weight and body mass index (BMI)
- If approved, the PA will be approved for 6 months

- Beneficiary must be compliant with Zepbound® usage (defined as 75% utilization) and compliant with positive airway pressure (CPAP or BiPAP) usage
- Beneficiary must demonstrate a positive response in OSA self-reported symptoms as compared to baseline (e.g., reduction in daytime sleepiness, reduction in snoring, or reduction in AHI) and decrease in weight/ body mass index (BMI)
- Beneficiary continues with comprehensive weight management program with behavioral modification, reduced-calorie diet, and increased physical activity.
 - Prescriber must submit the following:
 - Current chart notes
 - Current weight and body mass index (BMI)
 - o Documentation of patient specific symptoms improvement compared to baseline
 - Current CPAP or BiPAP usage report

QUANTITY EDITS:

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#4 injections/ 28 days

CRITERIA EFFECTIVE APRIL 16, 2025

5. SOFDRA (sofpironium bromide) 12.45% gel

SOFDRA is indicated for the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.

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 primary axillary hyperhidrosis with excessive sweating for at least 6 months despite the use of topical antiperspirants
- Beneficiary should not be approved or continue the medication if meets one of the following:
 - Diagnosed with secondary focal hyperhidrosis or Frey's Syndrome
 - Diagnosed with generalized hyperhidrosis, night sweats, or excessive sweating
- Prescriber must submit the following:
 - Current chart notes
 - o Documentation of products tried with response
 - Medical necessity over aluminum chloride-containing topical antiperspirants or has documented intolerance
- Initial approval would be for 3 months, subsequent approvals may be up to 6 months.

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to treatment with documentation of decreased sweating compared to baseline
- Prescriber must submit the following:
 - Current chart notes
 - Documentation of response to treatment

QUANTITY EDITS:

1 bottle (50mL)/ 30 days

6. ALHEMO (concizumab-mtci) 60 mg, 150 mg, and 300 mg injection

ALHEMO is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with:

- hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors
- hemophilia B (congenital factor IX deficiency) with FIX inhibitors

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 ٠ 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:
 - hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors, OR 0
 - hemophilia B (congenital factor IX deficiency) with factor IX inhibitors. 0
- •
- Beneficiary must meet <u>ONE</u> of the following: High factor VIII or IX inhibitor titer (≥5 Bethesda units per mL (BU)); OR
 - Factor VIII or IX inhibitor titer <5 BU/mL with inadequate response to high dose factor; 0
- Beneficiary must have been prescribed, or need, treatment with bypassing agents
- Beneficiaries must meet **ONE** of the following for confirming disease severity:
 - Severe disease with <1% of factor VIII or factor IX in blood while on factor products; **OR** 0
 - 0 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
- Beneficiary should not be approved or continue the medication if meets one of the following:
 - Continues to receive prophylaxis bypassing agents (e.g., rFVIIa or aPCC)
 - ALHEMO is ordered for breakthrough bleeding
 - Pregnant
- Request must be submitted by, or in consultation with, a hemophilia specialist or hemophilia . treatment center
- Prescriber must submit the following: .
 - Chart notes for the last 24 weeks with summary of bleeding events
 - Previous therapies tried with episodic or prophylactic bypassing agents (e.g., FEIBA®, NovoSeven RT®, or Sevenfact®)
 - Documentation of **ONE** of the following: \cap
 - Inadequate response to Immune Tolerance Induction (ITI); OR
 - Rationale why the beneficiary is not a candidate for ITI;
 - Current factor activity and annualized bleeding rate
 - Current labs including CBC 0
 - Negative pregnancy test results if applicable
 - Attestation that female beneficiary of reproductive potential has been counseled on the 0 importance of effective contraception
 - Attestation that beneficiary has been counseled on proper technique on episodic 0 treatment with bypassing agents as needed for breakthrough bleeding episodes Medical necessity over prophylaxis factor products and Hemlibra® for hemophilia A
 - Initial PA will be for 3 months, renewal PAs may be approved for up to 6 months.

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 0

7. TRYNGOLZA (olezarsen) 80 mg/0.8 mL injection

TRYNGOLZA is indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).

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 familial chylomicronemia syndrome (FCS) confirmed by molecular genetic test with fasting triglycerides level ≥ 880 mg/dL and multifactorial (polygenic) chylomicronemia has been ruled out
- Prescribed by, or in consultation with, a cardiologist, endocrinologist, or specialist experienced in treating severe hypertriglyceridemia
- Beneficiary should not be approved or continue the medication if meets one of the following:
 - Not on a low-fat diet of ≤ 20 gm of fat per day
 - Currently smoker
- Prescriber must submit the following:
 - o Current chart notes with genetic testing to confirm diagnosis
 - Previous medications tried for lowering triglycerides
 - Current fasting labs including lipid panel
 - Documentation of symptoms associated with FCS (e.g., fatigue, pancreatitis/ abdominal pain, eruptive xanthomas, lipemia retinalis, hepatosplenomegaly)
 - Attestation that beneficiary is on a low-fat diet with ≤20 gm of fat per day
- Initial PA will be for 3 months, renewal PAs may be up to 6 months

RENEWAL REQUIREMENTS:

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with decrease in fasting triglycerides and decrease in symptoms documented at baseline
 - Prescriber must submit the following:
 - Current chart notes
 - Current fasting labs including lipid panel
 - Current documentation of symptoms
 - Attestation that the beneficiary remains on low-fat diet with ≤ 20 gm of fat per day

QUANTITY EDITS:

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1 injection per 30 days

CRITERIA EFFECTIVE APRIL 16, 2025

8. ONAPGO (apomorphine) 98 mg/20 mL injection

ONAPGO is indicated for the treatment of motor fluctuations in adults with advanced Parkinson's disease.

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.
- 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., hemolytic anemia, reduced resting blood pressure, increase in falls, psychotic-like behavior, etc.)

- Beneficiary must continue to have motor fluctuations with a minimum of 3 hours of "Off" time per day
- Beneficiary should not be approved or continue the medication if meet one of the following:
 - Requires the concomitant use of 5HT3 antagonists (e.g., ondansetron, granisetron, dolasetron, palonosetron)
 - Develops significant daytime sleepiness that interferes with normal daily function (e.g., conversations, eating, driving)
 - o Drinks alcohol
 - Has severe renal or severe hepatic impairment
 - o Pregnant
- Prescriber must submit the following:
 - Current chart notes
 - Current symptoms of Parkinson's Disease
 - Negative pregnancy test for female patient of reproductive potential
 - Average number of "Off" hours per day
 - Medical necessity over increasing the dose on long and short acting oral carbidopa/levodopa products

- 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., excessive daytime sleepiness, increase in falls, hemolytic anemia, psychotic-like behavior, etc.)

CRITERIA EFFECTIVE APRIL 16, 2025

9. GOMEKLI (mirdametinib) 1 mg & 2 mg capsules and 1 mg tablet for oral suspension

GOMEKLI is indicated for the treatment of adult and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection.

NOTE: This criteria will be listed in the Prior Authorization Criteria for Select Oncology Medications document located on the Prime Therapeutics website at: <u>https://ar.primetherapeutics.com/documents/d/arkansas/prior-authorization-criteria-for-select-oncology-medications-05172024</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 neurofibromatosis type 1 (NF1) and have symptomatic plexiform neurofibromas (PN) not amenable to complete resection <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-bycase basis.
- Beneficiary must have at least ONE measurable PN <u>AND</u> either a positive genetic test for NF1 <u>OR</u> have at least ONE other diagnostic criteria listed below:
 - o 6 or more café'-au-lait macules; OR
 - Freckling in axilla or groins; OR
 - Optic glioma; OR
 - 2 or more Lisch nodules; OR
 - Distinctive body lesion; OR
 - First-degree relative with NF1

- Beneficiary should not be approved or continue the medication if meets one of the following:
 - Diagnosed with retinal vein occlusion (RVO) or retinal pigment epithelium detachment (RPED)
 - Has left ventricular ejection fraction (LVEF) <55% at baseline, or has an absolute decrease in LVEF 20% or greater from baseline after treatment begins
 - o Is pregnant
 - Has uncontrolled hypertension
 - History of glaucoma
 - Alanine transaminase (ALT) > 2X ULN
 - Is unable to tolerate GOMEKLI after one dose reduction
- Prescriber must submit the following:
 - o Current chart notes with status of plexiform neurofibromas
 - Current baseline left ventricular ejection fraction (LVEF)
 - Previous therapies tried including any surgery
 - o Documentation of comprehensive ophthalmic assessment
 - Current body surface area (BSA) for dose determination (Dosed 2mg/m² twice daily for 21 days of each 28-day cycle)
 - Current labs including CBC, LFTs and creatine phosphokinase
 - Attestation that female patient of reproductive potential is using contraception
 - Medical necessity over Koselugo® (selumetinib)
- Initial PA will be for 3 months, renewal PAs may be approved for up to 6 months

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary should have an improvement with size or quantity of plexiform neurofibroma(s) after 9 months of treatment
- Prescriber must submit the following:
 - Current chart notes with documentation of response to therapy
 - Documentation of left ventricular ejection fraction (LVEF) every 3 months during the first year
 - Current body surface area for dose determination
 - Current labs including CBC, LFTs and creatine phosphokinase
 - o Attestation that female patient of reproductive potential is using contraception

QUANTITY EDITS:

- 1 mg—#84/ 28 days (capsule available in package size of 42; tablets available in package sizes of 42 and 84)
- 2 mg—#84/ 28 days (available in package sizes of 42 and 84)

CRITERIA EFFECTIVE APRIL 16, 2025

10. INZIRQO (hydrochlorothiazide) 10 mg/mL suspension

INDICATION:

- Treatment of hypertension in adult and pediatric patients, to lower blood pressure.
- Treatment of edema associated with congestive heart failure, hepatic cirrhosis, and renal disease including the nephrotic syndrome in adult and pediatric patients.

APPROVAL CRITERIA:

POINT-OF-SALE (POS) EDITS:

- Patients under 7 years of age or have a diagnosis of NPO in the last 365 days; AND
- Billed diagnosis of hypertension or edema in the last 2 years
- For patients 7 years of age and older, attestation of NPO status will be required every 6 months (effective 8/1/2025)

PATIENTS NOT MEETING POS 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 hypertension or edema associated with congestive heart failure, hepatic cirrhosis, or renal disease <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.
- Prescriber must submit the following:
 - Current chart notes
 - Baseline blood pressure or description of edema
 - o Medical necessity over hydrochlorothiazide tablets and capsules

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary should have an improvement with underlying diagnosis
- Prescriber must submit the following:
- Current chart notes
 - Current blood pressure or description of edema
 - o Continued medical necessity of Inzirqo[™] suspension over oral solid dosage forms

QUANTITY EDITS:

• 2 bottles per month (If patient requires a higher dose, a quantity override can be entered.)

CRITERIA EFFECTIVE APRIL 16, 2025

11. XROMI (hydroxyurea) 100 mg/mL solution

XROMI is indicated to reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients aged 6 months of age and older with sickle cell anemia with recurrent moderate to severe painful crises.

APPROVAL CRITERIA:

Point-of-sale (POS) edit

- Patients under 7 years of age or have a diagnosis of NPO in the last 365 days; AND
- Billed diagnosis of sickle cell disease in the last 2 years
- For patients 7 years of age and older, attestation of NPO status will be required every 6 months (effective 8/1/2025)

Patients not meeting POS criteria

- Beneficiary must be diagnosed with moderate to severe, painful crises associated with sickle cell anemia
- Prescribed by, or in consultation with, a specialist in the treatment of sickle cell.
- Prescriber must submit the following:
 - Current chart notes with documentation of pain crises and blood transfusion frequency
 - Medical necessity for the use of solution over capsules which are available without prior authorization
 - Negative pregnancy test if a female of reproductive potential
 - Attestation that female patients of reproductive potential will be using effective contraception
 - o Attestation that labs will be monitored throughout treatment

RENEWAL REQUIREMENTS:

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate an improvement in frequency of pain crises and transfusions
- Prescriber must submit the following:
 - Current chart notes
 - Continued medical necessity for the use of oral solution over capsules
 - Attestation that female patients of reproductive potential will continue to use effective contraception

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.
 - <u>https://humanservices.arkansas.gov/divisions-shared-services/medical-services</u>
 - https://humanservices.arkansas.gov/
 - 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: https://humanservices.arkansas.gov/divisions-shared-services/medical-services/

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. <u>REGARDING MANUAL REVIEW PA REQUESTS</u>:

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 in an emergency 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: https://ar.primetherapeutics.com/provider-documents 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 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.