ARKANSAS DEPARTMENT OF HUMAN SERVICES

Division of Medical Services
Pharmacy Program

P.O. Box 1437, Slot S415 · Little Rock, AR 72203-1437
Phone: 501-683-4120 · Fax: 1-800-424-5851

MEMORANDUM

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

FROM: Jason Derden, Pharm.D. Division of Medical Services Pharmacy Program

DATE: **May 30, 2017**

SUBJ: **AR Medicaid PA edits approved at the AR Medicaid DUR Board APRIL 19, 2017 meeting and PDL changes approved by the PDL Drug Review Committee meeting MAY 10, 2017**

ADDITIONS TO THE AR MEDICAID PREFERRED DRUG LIST (PDL): Please see the PDL list below for specific Preferred-status and Non-preferred status agents in the following categories that are being added to the PDL: topical corticosteroid agents; drugs for treating glaucoma; ophthalmic antibiotic agents; ophthalmic antibiotic-steroid combination agents; short-acting narcotic analgesic agents.

CHANGES TO EXISTING PA CRITERIA OR EXISTING CLAIM EDITS: Maximum Daily Morphine Milligram Equivalent (MME) edit decreased; Topical Corticosteroid quantity edits revised; preferred PPI (omeprazole 20 mg capsule, pantoprazole 20 mg and 40 mg tablet) revised approval criteria; Orkambi® (lumacaftor/ivacaftor) tablet continuation criteria clarified.

NEW CLINICAL EDITS THROUGH MANUAL REVIEW PRIOR APPROVAL (PA) PROCESS: Rubraca™ (rucaparib) tablet; Impavido® (miltefosine) capsule; Ryvent™ (carbinoxamine maleate) tablet; Migergot® (ergotamine/caffeine) suppository; Ilaris® (canakinumab) injection; Emflaza™ (deflazacort) tablet and suspension; Eucrisa™ (crisaborole) ointment.

NEW CLAIM EDITS, INCLUDING DOSE-OP, DAILY DOSE/QUANTITY EDITS, CUMULATIVE QUANTITY EDIT, And ACCUMULATION EDITS: Quantity edits for Lidocaine 5% Ointment; Biltricide® (praziquantel) tablet; Albenza® (albendazole) tablet; Cyclobenzaprine tablets;

All criteria for the point of sale (POS) clinical edits and claim edits can be viewed on the Medicaid website at https://arkansas.magellanrx.com/provider/documents .

Medicaid Pharmacy Program drug reimbursement rate methodology changed April 1, 2017; reimbursement rates stated in this memo are informational only and are only current as of the date the memo was drafted; the rates stated are approximate as they have been rounded.

REMINDERS:

1) **The Maximum Daily Morphine Milligram Equivalent (MME) Dose DECREASED MAY 9, 2017 to ≤ 250 MME/day for non-cancer chronic pain beneficiaries. Incoming opioid claims that will cause the total MME/day to exceed 250 MME/day (>250 MME/day) will reject at point of sale whether from same prescriber or different prescribers.**

The Medicaid Pharmacy Program will continue reducing the maximum allowed Morphine Milligram Equivalent (MME) daily dose for chronic pain non-cancer patients by 50 MME approximately every 6 months to *reduce the overdose risk* and other risks associated with opioid use. *The ultimate Medicaid goal is to reduce the TOTAL MME PER DAY for chronic non-cancer pain patients to meet the CDC recommendations.*

*Per the CDC, "**Opioids are not first-line therapy**" for chronic pain.* Although opioids can reduce pain during *short-term use,* the clinical evidence review found *insufficient evidence* to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.

Per the CDC Guideline for Prescribing Opioid for Chronic Pain, 2016, the CDC recommendations regarding opioid MME daily dose include the following:

- Most experts agreed that, in general, increasing dosages to *50 MME/day or more increases overdose risk without* necessarily *adding benefits* for pain control or function.
- The CDC considers *high opioid dosages* ≥ *90 MME/day*.
- Benefits of *high-dose opioids* for chronic pain are not established.
- Risks for *serious harms related to opioid therapy increase* at higher opioid dosage.
- *Concurrent use of benzodiazepines and opioids is likely to put patients at greater risk for potentially fatal overdose*, particularly if benzodiazepine(s) are combined with higher dosages of opioids ≥ 50 MME/day. Concurrent opioid and benzodiazepine prescribing should be avoided.

2) **The Medicaid allowed quantity edit for a short-acting opioid for non-cancer patients was reduced on April 26, 2016 from 124 units to a maximum of *93 units for a 31-day supply*. Continuing to allow a daily dose of 6 units per day was intended for short-term *acute pain situations* only and not for chronic pain prescriptions that are dispensed monthly.** Dispensing 90 units and shortening the days' supply to 15 days increases the calculated daily MME dose. *For example, oxycodone IR 30 mg #90 submitted with a 15 days' supply = **270 MME/day**. **Effective May 9, 2017, a claim for oxycodone 30 mg #90/15 days' supply will reject at point of sale for exceeding the total daily MME.*** Shortening the days' supply on a submitted claim does not allow the next short-acting opioid prescription to be filled sooner because the quantity limit per prescription is also an *accumulation quantity limit* that includes all SA opioids the beneficiary received in the previous 31 days and cannot be overridden without a prior approval.

3) REGARDING MANUAL REVIEW PA REQUESTS: Drugs that require a clinical manual review PA, requests for a drug as an *exception* to established point of sale prior approval criteria algorithm, and requests for non-preferred drugs on the PDL, are reviewed on a case-by-case basis. Prescribers must provide a letter explaining the medical necessity for the requested drug along with all written documentation, e.g., chart notes, pharmacy printouts for cash and private insurance paid drugs, lab results, etc., to substantiate the medical necessity of the request. ***Please note that starting the requested drug, including long-acting injectable antipsychotic agents, prior to a PA request being reviewed and approved, through either inpatient use, by using office "samples", or by any other means, does not necessitate Medicaid Pharmacy Program approval of the PA request.***

A. PDL CHANGES, EFFECTIVE JULY 1, 2017:

ADDITIONS BELOW TO THE PREFERRED DRUG LIST (PDL) FROM THE MAY 10, 2017 PDL DRUG REVIEW COMMITTEE MEETING*

(**existing or revised quantity edits for drugs on the PDL remain in place in all categories*)

1) TOPICAL CORTICOSTEROID AGENTS (*see revised quantity edits on page 7 of this memo*):
CATEGORY IS NEW TO PDL
Note: all preferred status topical corticosteroids are for generic formulation unless otherwise stated

Potency Class 1 – Superpotent, *Preferred Status* only for package sizes noted:
Clobetasol propionate 0.05% cream-emollient, 15 gm, 30 gm, 60 gm
CLOBEX® (clobetasol propionate) (Brand only) 0.05% topical lotion, 59 ml
Halobetasol propionate 0.05% cream, 15 gm, 50 gm
Halobetasol propionate 0.05% ointment, 15 gm, 50 gm

Potency Class 1 – Superpotent, *Non-Preferred Status*, for all package sizes unless otherwise noted:
Betamethasone dipropionate augmented 0.05% gel,
Betamethasone dipropionate augmented 0.05% oint,
Clobetasol propionate 0.05% cream,
Clobetasol propionate 0.05% gel
Clobetasol propionate 0.05% ointment
Clobetasol propionate 0.05% shampoo
Clobetasol 0.05% solution
clobetasol propionate 0.05% foam
Clobetasol propionate 0.05% emollient foam
Clobetasol propionate 0.05% spray
Clobetasol propionate 0.05% topical lotion, generic 59 ml, brand and generic 118 ml
Diflorasone diacetate 0.05% ointment
Fluocinonide 0.1% cream
Halobetasol propionate 0.05% lotion
Betamethasone dipropionate augmented 0.05% lotion
Desoximetasone 0.25% spray

Potency Class 2 – Potent, *Preferred Status* only for package sizes noted:
Betamethasone dipropionate Aug. 0.05% cream, 15 gm, 50 gm
Fluocinonide 0.05% cream, 15 gm, 30 gm, 60 gm
Fluocinonide 0.05% ointment, 15 gm, 30 gm
Triamcinolone 0.5% ointment, 15 gm

Potency Class 2– Potent, *Non-Preferred Status*, for all package sizes unless otherwise noted:
Amcinonide 0.1% ointment
Desoximetasone 0.05% gel
Desoximetasone 0.25% cream
Desoximetasone 0.25% oint
Diflorasone 0.05% cream
Fluocinonide 0.05% gel
Fluocinonide 0.05% solution
Halcinonide 0.1% cream
Halcinonide 0.1% ointment
Fluocinonide 0.05% cream, 120 gm
Fluocinonide 0.05% ointment, 60 gm

Potency Class 3 – Upper-Mid Strength, *Preferred Status* only for package sizes noted:
Betamethasone valerate 0.1% ointment, 15 gm, 45 gm
ELOCON® (mometasone furoate) (Brand only) 0.1% ointment, 15 gm, 45 gm
Betamethasone dipropionate 0.05% (not augmented) Lotion, 60 ml
Triamcinolone 0.5% cream, 15 gm

Potency Class 3 – Upper-Mid Strength, *Non-Preferred Status* for all package sizes unless otherwise noted:
Betamethasone valerate 0.12% foam
Fluticasone propionate 0.005% ointment
Triamcinolone 0.1% ointment
Amcinonide 0.1% cream
Amcinonide 0.1% lotion
Betamethasone dipropionate 0.05% cream (not augmented)
Betamethasone dipropionate 0.05% ointment (not augmented)
Betamethasone dipropionate 0.05% spray emulsion (not augmented)
Fluocinonide 0.05% emollient cream

Potency Class 4 – Mid Strength, *Preferred Status* only for package sizes noted:
ELOCON® (Mometasone furoate) 0.1% (Brand only) cream, 15 gm 45 gm
Mometasone furoate 0.1% solution or lotion, 30 ml
Fluocinolone 0.025% ointment, 15 gm, 60 gm, 120 gm
Triamcinolone 0.1% cream, 15 gm, 28.4 gm, 30 gm, 45 gm, 80 gm, 85.2 gm

Potency Class 4 – Mid Strength, *Non-Preferred Status* for all package sizes unless otherwise noted:
Clocortolone pivalate 0.1% cream and cream pump
Hydrocortisone valerate 0.2% ointment
Mometasone furoate 0.1% solution or lotion, 60 ml
Flurandrenolide 0.05% ointment
Triamcinolone acetonide 0.1% aerosol spray
Desoximetasone 0.05% cream
Desoximetasone 0.05% ointment
Triamcinolone 0.1% cream, 454 gm, 453.6 gm

Potency Class 5 – Lower-Mid Strength, *Preferred Status* only for package sizes noted:
Fluocinolone 0.01% cream, 15 gm, 60 gm
Betamethasone valerate 0.1% cream, 15 gm, 45 gm
Fluocinolone 0.025% cream, 15 gm, 60 gm, 120 gm
Fluticasone propionate 0.05% cream, 15 gm, 30 gm, 60 gm
Hydrocortisone butyrate 0.1% solution
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 Status* for all package sizes unless otherwise noted:
Desonide 0.05% lotion
Desonide 0.05% ointment
Fluocinolone shampoo
Betamethasone valerate 0.1% lotion
Flurandrenolide 0.05% cream
Flurandrenolide 0.05% lotion
Flurandrenolide 4 mcg/sq. cm tape, small and large size

continued **Potency Class 5 – Lower-Mid Strength, *Non-Preferred Status* for all package sizes unless otherwise noted:**
Fluticasone propionate 0.05% lotion
Hydrocortisone butyrate 0.1% cream
Hydrocortisone butyrate 0.1% cream emollient
Hydrocortisone butyrate 0.1% ointment
Hydrocortisone valerate 0.2% cream
Hydrocortisone probutate 0.1% cream
Prednicarbate 0.1% cream emollient
Prednicarbate 0.1% ointment
Triamcinolone 0.05% ointment, 430 gm
Triamcinolone 0.025% ointment, 453.6 gm, 430 gm

Potency Class 6 – Mild, *Preferred Status* only for package sizes noted:
Alclometasone dipropionate 0.05% ointment, 15 gm, 45 gm, 60 gm
SYNALAR® (fluocinolone) 0.01% (Brand only) solution, 60 ml
Triamcinolone 0.025% cream, 15 gm, 60 gm, 80 gm

Potency Class 6 – Mild, *Non-Preferred Status* for all package sizes unless otherwise noted:
Fluocinolone 0.01% solution, 90 ml
Triamcinolone 0.025% cream, 453.6 gm, 454 gm
Alclometasone dipropionate 0.05% cream
Desonide 0.05% gel
Desonide 0.05% cream
Fluocinolone scalp oil 0.01%

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 0.5% oint (covered OTC), 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 Status* for all package sizes unless otherwise noted:
Hydrocortisone 1% cream, 453.6 gm
Hydrocortisone 1% ointment, 453.6 gm
Hydrocortisone 2.5% cream 453.6 gm
Hydrocortisone 2.5% ointment, 453.6 gm, 454 gm
Hydrocortisone 1% ointment in absorbase
Hydrocortisone 2.5% lotion
Hydrocortisone 2.5% solution

2) AGENTS FOR TREATING GLAUCOMA:
CATEGORY IS NEW TO PDL
Preferred Status only for strengths and package sizes noted:
Latanoprost 0.005%, 2.5 ml solution drops
TRAVATAN Z® (travoprost) 2.5 ml, 5 ml solution drops
LUMIGAN® 0.01% (bimatoprost) solution drops 2.5ml, 5ml
Levobunolol 0.5% solution drops, 5 ml, 10 ml, 15 ml
Carteolol 1% solution drops, 5 ml, 10 ml, 15 ml
Timolol 0.25%, 0.5% solution drops, 5 ml, 10 ml, 15 ml
Dorzolamide 2% solution drops, 10 ml
ALPHAGAN® P (brimonidine) 0.15% solution drops (Brand only), 5 ml, 10 ml, 15 ml
SIMBRINZA® (bromonidine 1%/ brinzolamide 0.2%) suspension drops, 8ml
COMBIGAN® (brimonidine 0.2%/ timolol 0.5%) solution drops 5 ml, 10 ml, 15 ml
Dorzolamide /timolol 22.3- 6.8 mg/ml solution drops, 10 ml

Non-Preferred Status, all package sizes unless otherwise noted:
LUMIGAN® (bimatoprost) 0.01% solution drops, 7.5 ml
Bimatoprost 0.03% solution drops
Pilocarpine 1%, 2%, 4% solution drops
Brimonidine 0.2%, 0.15% solution drops
ALPHAGAN® P (brimonidine) 0.1% drops
Apraclonidine 0.5%, 1% solution drops
Betaxolol 0.5% solution drops
BETOPIC S® (betaxolol) 0.25% solution drops
Metipranolol 0.3% solution drops
ISTALOL® (timolol maleate) 0.5% solution drops

continued **Non-Preferred Status for Drugs Treating Glaucoma**
Timolol gel forming solution 0.25%, 0.5% (same as TIMOPTIC-XE®)
Timolol preservative free ocudose 0.25%, 0.5%
AZOPT® (brinzolamide) suspension drops 1%
ZIOPTAN® (tafluprost) solution drops 0.0015%
COSOPT® PF (dorzolamide 2% /timolol 0.5%) solution drops

3) OPHTHALMIC ANTIBIOTIC AGENTS
CATEGORY IS NEW TO PDL
Preferred Status:
Polymyxin B /trimethoprim ophthalmic solution drops
Bacitracin/ polymyxin B ophthalmic solution drops
Tobramycin 0.3% ophthalmic solution drops
Gentamicin 0.3% ophthalmic solution drops
Gentamicin 0.3% ophthalmic ointment
Erythromycin 0.5% ophthalmic ointment
VIGAMOX® (moxifloxacin) 0.5% ophthalmic solution drops
Ciprofloxacin ophthalmic solution drops

Non-Preferred Status:
TOBREX® (tobramycin) 0.3% ointment
BESIVANCE® (besifloxacin) 0.6% ophthalmic suspension drops
CILOXAN® (ciprofloxacin) 0.3% ophthalmic solution drops
CILOXAN® (ciprofloxacin) 0.3% ophthalmic ointment
ZYMAXID® (gatifloxacin) 0.5% ophthalmic solution drops
Levofloxacin 0.5% ophthalmic solution drops
MOXEZA® (moxifloxacin) 0.5% ophthalmic solution drops
Ofloxacin 0.3% ophthalmic solution drops
AZASITE® (azithromycin) 1% ophthalmic solution drops
Bacitracin ophthalmic ointment 500 units/gm
NATACYN® (natamycin) 5% ophthalmic suspension drops
Neomycin/polymyxin B/ bacitracin ophthalmic ointment
Neomycin/polymyxin B/ gramicidin ophthalmic solution drops
Sulfacetamide 10% ophthalmic solution drops

4) OPHTHALMIC ANTIBIOTIC-STEROID AGENTS
CATEGORY IS NEW TO PDL
Preferred Status:
Neomycin sulfate /polymyxin B/ dexamethasone ophthalmic ointment
Neomycin sulfate /polymyxin B/ dexamethasone 0.1% ophthalmic suspension drops
TOBRADEX® (tobramycin / dexamethasone) 0.3%/ 0.1% ophthalmic ointment
Tobramycin 0.3%/dexamethasone 0.1% ophthalmic suspension drops
Sulfacetamide sodium 10% / prednisolone sodium phosphate 0.23% ophthalmic solution drops

Non-Preferred Status:
TOBRADEX® ST (tobramycin / dexamethasone) 0.3%/0.05% ophthalmic suspension drops
Neomycin 3.5 mg/ polymyxin B sulfates 10K / hydrocortisone 1% ophthalmic suspension drops
Neomycin sulfate/ polymyxin B sulfates/ bacitracin zinc/ hydrocortisone ophthalmic ointment
ZYLET® (loteprednol 0.5%/tobramycin 0.3%) ophthalmic suspension drops
PRED-G® (gentamicin sulfate 0.3%/prednisolone acetate 0.6%) ophthalmic ointment
PRED-G® (gentamicin sulfate 0.3%/prednisolone acetate 1%) ophthalmic suspension drops
BLEPHAMIDE® S.O.P. (sulfacetamide sodium 10%/ prednisolone 0.2%) ophthalmic ointment
BLEPHAMIDE® (sulfacetamide sodium 10% / prednisolone 0.2%) ophthalmic suspension drops

5) SHORT-ACTING NARCOTIC ANALGESIC AGENTS
CATEGORY IS NEW TO PDL
Preferred Status only for strengths noted: *(Quantity edits, MME edits, accumulation edits, and refill too soon edits apply)*
Acetaminophen-codeine tablet 300-15 mg, 300-30 mg, 300-60 mg
Acetaminophen-codeine elixir or solution120 mg-12 mg/5 ml in 118 ml and 473 ml bottle sizes,
Codeine tablet 15 mg, 30 mg, 60 mg,
Hydrocodone / acetaminophen tablet 5/325 mg, 7.5/325 mg, 10/325 mg
Hydrocodone/ acetaminophen oral solution 7.5-325 mg/15 ml
Hydrocodone/ibuprofen tablet 7.5/200 mg
Hydromorphone tablet 2 mg, 4 mg, 8 mg
Morphine IR tablet 15 mg, 30 mg,
Morphine oral solution 10 mg/5 ml, 20 mg/5 ml,
Morphine concentrated oral solution 100 mg/5 ml
Meperidine tablet 50 mg
Meperidine oral solution 50 mg/ 5 ml
Oxycodone tablet 5 mg, 10 mg, 15 mg, 20 mg, 30 mg

***continued* Preferred Status only for strengths noted**
Oxycodone oral solution 5 mg/ 5 ml
Oxycodone/ acetaminophen tablet 5 mg-325 mg, 7.5 mg-325mg, 10mg – 325 mg
Oxycodone/ acetaminophen solution 5-325 mg/ 5 ml
Tramadol tablet 50 mg
Tramadol/ acetaminophen tablet 37.5 mg-325 mg

Non-Preferred Status for all strengths unless otherwise noted
Acetaminophen-codeine elixir or solution 120 mg-12 mg/5 ml unit dose cups, and 300 mg-30 mg/12.5 ml unit dose cups
Hydrocodone / acetaminophen tablet, 5-300 mg,7.5-300 mg, 10-300 mg, 2.5-325 mg,
hydrocodone/APAP Oral Solution *Unit Dose Cups* 7.5-325 mg/15 ml, 5-163 mg/7.5 ml, 10-325 mg/ 15 ml, 2.5-108 mg/ 5 ml, 5-217 mg/ 10 ml,
ZAMICET® (hydrocodone/APAP) 10 mg-325 mg/15 ml oral solution
Hydrocodone-ibuprofen tablet 10 mg-200 mg, 5 mg-200 mg
REPREXAIN™ (hydrocodone/ibuprofen) 2.5 mg-200 mg tablet
Meperidine tablet 100 mg
Oxycodone capsule 5 mg
Oxycodone concentrated oral solution 20 mg/ml
Oxycodone 10 mg/ 0.5 ml oral syringe
Oxycodone/ acetaminophen 2.5 mg-325 mg,
PRIMLEV™ (oxycodone/APAP) 5 mg-300 mg, 7.5 mg-300 mg, 10 mg-300 mg
Oxycodone/aspirin
Oxycodone/Ibuprofen tablet 5 mg-400 mg
Hydromorphone 1 mg/1 ml oral solution
Hydromorphone 3 mg rectal suppository
OPANA® (oxymorphone) tablets
NUCYNTA® (tapentadol) tablet and oral solution
Butorphanol 10 mg/ml nasal spray
FIORINAL® with codeine No. 3
butalbital/caffeine/APAP w/codeine 50 mg-325 mg-30 mg, and 50 mg-300 mg-30 mg
Butalbital compound w/codeine
Pentazocine/naloxone tablet
Dihydrocodeine/APAP/caffeine 320.5 mg- 30 mg
Carisoprodol Compound w/Codeine
FIORICET® with CODEINE 50 mg-300 mg-30 mg
CAPITAL® and CODEINE (acetaminophen with codeine) oral suspension 120 mg-12 mg/ 5 ml

PDL PA Call Center 1-800-424-7895; t**he PDL FAX number is 1-800-424-5739.**

EFFECTIVE NOVEMBER 8, 2017

B. CHANGES TO EXISTING PA CRITERIA OR CLAIM EDITS:

1) **The Maximum Daily Morphine Milligram Equivalent (MME) Dose will DECREASE to ≤ 200 MME/day** for non-cancer chronic pain beneficiaries. Incoming opioid claims that will cause the total MME/day to exceed 200 MME/day (>200 MME/day) *will reject at point of sale* whether from same prescriber or different prescribers. *Please begin titrating the doses downward to prevent claims rejecting at point of sale.*

The Medicaid Pharmacy Program will continue reducing the maximum allowed Morphine Milligram *Equivalent (MME) daily dose for chronic pain non-cancer patients by 50 MME approximately every 6 months* (≤ 150 MME/day in May 2018, ≤ 100 MME in November 2018) to *reduce the overdose risk* and other risks associated with opioid use until the daily MME is closer to the recommendations from the CDC and CMS.

The Medicaid pharmacy program system converts the dose of all oral and transdermal opioid drug claims to morphine milligram equivalents (MME) per day *based on the quantity dispensed and the days' supply submitted* by the pharmacy provider on the opioid claim. For patients who fill opioid prescriptions early, the calculated daily MME *includes claims in history if* the incoming claim is being *filled early* and has *3 days or more* overlapping with the days' supply of the claim(s) in history. If this happens, the incoming claim and the claim(s) in history will both be included in the daily MME calculation and could cause the incoming claim to reject due to calculated high MME.

EFFECTIVE JULY 19, 2017:

The maximum daily MME will be limited to a total of **90 MME/day** for Medicaid beneficiaries who are new to Medicaid who do not have opioid drug claims in Medicaid history in the previous 60 days. This **90 MME/day** rule will also apply for *existing* Medicaid beneficiaries who may not be new to Medicaid but are "new starts" on opioid drugs or for other reasons do not have an opioid drug claim in Medicaid history in the previous 60-

days (e.g., previously paying cash for opioids). Prescribers may submit chart notes and applicable documentation to request prior authorization for doses above 90 MME/day for "new starts".

Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.

EFFECTIVE: July 1, 2017:

2) **Topical Corticosteroid Agents, changes to the potency category and changes in quantity edits:**
The topical corticosteroid agents have been moved to the PDL program. Please refer to the beginning of this memo for the list of preferred and non-preferred agents in the topical corticosteroid drug class. Please also note that the topical corticosteroid agents have been re-categorized in the Medicaid system from four potency categories to seven potency classes, with Class-1 containing the superpotent agents and Class-7 containing the least potent agents. Some of the larger package sizes of preferred agents may be listed as non-preferred status and will require prior authorization and the prescriber must provide specific information for frequency of administration, length of therapy, and the body surface area being treated in order for the request to be reviewed. The existing point of sale prior approval criteria that allowed for approval of certain agents at point of sale will be removed on the date that these agents move to PDL status where agents will be listed as either preferred status or non-preferred status. All non-preferred status drugs require manual review PA through the PDL call center. Other drugs that include the use of a topical corticosteroid in the approval algorithm have been revised to reflect the reassigned potency classes.

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. Quantities greater than 240 gm or quantities for the larger package size of a solution or lotion will require manual review prior authorization and will require the prescriber to provide specific information for frequency of administration, length of therapy, and the body surface area being treated in order for the request to be reviewed.

PDL PA Call Center 1-800-424-7895; the PDL FAX number is 1-800-424-5739.

EFFECTIVE: JULY 19, 2017:

3) **Proton Pump Inhibitors (PPI), revised CPT codes in approval criteria:**
Preferred PPI agents include omeprazole 20 mg capsule, pantoprazole 20 mg and 40 mg tablet.
Reimbursement rates:
NADAC Generic omeprazole 20 mg capsule = $0.04787 ea.
NADAC Generic pantoprazole 20 mg tablet = $0.09065 ea.
NADAC Generic pantoprazole 40 mg tablet = $0.0641 ea.

The current Point-of-Sale Prior Authorization (PA) approval criteria for the PPI agents listed as "preferred with criteria" status are as follows:

- Approve up to 93 days of preferred proton pump inhibitor therapy per year for all beneficiaries age 15 months or older; OR
- Approve preferred proton pump inhibitor therapy beyond 93 days for beneficiaries 15 months or older who have a diagnosis in Medicaid history for Zollinger-Ellison Syndrome, Barrett's esophagus, Cystic Fibrosis (CF), pancreatic insufficiency, unspecified disease of pancreas, or has an endoscopy CPT code in Medicaid history in the previous 24 months.

The point of sale prior authorization (PA) criteria regarding the endoscopy CPT codes have been revised and additional CPT codes for endoscopy have been added to the approval list. The complete list of CPT codes is available for review on the Medicaid website at https://arkansas.magellanrx.com/provider/docs/rxinfo/PACriteria.pdf.

PDL PA Call Center 1-800-424-7895; the PDL FAX number is 1-800-424-5739.

EFFECTIVE IMMEDIATELY

4) **ORKAMBI® (lumacaftor 200 mg /ivacaftor 125 mg, or 100/125 mg) tablet, clarified continuation criteria:**
WAC reimbursement rate: 100-125 mg tablet or 200-125 mg tablet = $177.88 each tablet;

28 day supply = $19,923

ORKAMBI is a combination of lumacaftor and ivacaftor. ORKAMBI is indicated for the treatment of Cystic Fibrosis (CF) in patients who are age 6 years and older and are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. The efficacy and safety of ORKAMBI have not been established in patients with CF other than those homozygous for the F508del mutation.

The dose for patients, age 6 years through 11 years, is two lumacaftor 100 mg/ivacaftor 125 mg tablets every 12 hours. The dose for age 12 years and older has not changed and is still two lumacaftor 200 mg/ivacaftor 125 mg tablets every 12 hours.

The manual review prior authorization (PA) for the initial approval of Orkambi through the first year has not changed, and each approved PA will not exceed 3 months during the first year of treatment as specific lab data (ALT, AST, bilirubin) are required every 3 months. The initial approval criteria is as follows:

- Must be ≥Age 6 years; AND
- Must have CF with homozygous for the F508del mutation in the CFTR gene; AND
- Provide the calculated Child-Pugh score AND the labs (INR, Bilirubin, Albumin) AND chart notes (for encephalopathy and ascites) required to calculate the Child-Pugh score; AND
- Liver function lab results must be submitted with every PA request, AND
    - For the initial PA approval and continuation reviews, the liver function lab results for ALT or AST must be less than 3 times the upper limit of normal (ULN) with bilirubin elevations less than 2 times the ULN, OR the liver function lab results for ALT or AST must be less than 5 times the upper limit of normal without bilirubin elevation;
    - Lab results must be measured and submitted every 3 months during the 1st year, then every 6 months;

The denial criteria for a PA has not changed and is as follows:

• Patients with an active colonization with organisms such as Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abscessus; OR
• Patients who had 3 or more abnormal liver function tests (ALT, AST, AP, GGT ≥3 × the ULN or total bilirubin ≥2 × the ULN); OR
• Tobacco use;

All manual review PA requests for continuation criteria after 12 months of therapy are on a case-by-case basis. After the beneficiary has received 12 months of Orkambi treatment, in addition to continuing to monitor the liver function lab results every 6 months, the prior approval continuation will be dependent upon the review of several key clinical areas in order to determine an overall positive treatment response to the drug. The current medical results and chart notes will be compared to the previous medical history for an overall picture of the patient's progress, stabilization, or decline in health. The clinical review will continue to include reviewing ppFEV$_1$, BMI or weight, pulmonary exacerbations and exacerbations requiring hospitalization, and patient overall Quality of Life (QoL) using one of the specific validated questionnaires (CFQ 14+ for teenagers and adults; CFQ-Child, ages 6 through 13; CFQ Child P, a parent-proxy evaluation for children aged 8–13, or CFQ-R (Cystic Fibrosis Questionnaire-Revised)). After the first year, each approved PA will not exceed 6 months.

Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.

EFFECTIVE IMMEDIATELY:

C. NEW CLINICAL EDITS THROUGH MANUAL REVIEW PRIOR APPROVAL (PA) PROCESS:

1) RUBRACA™ (rucaparib) tablet, film coated, 200 mg, 300 mg:

The WAC reimbursement rate is $114.50 each tablet; Package size available in bottles of 60 tablets. A 30-day supply (@4 per day, or #120 tablets) = $13,740.

Rubraca™ is indicated as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca. This indication is FDA approved under accelerated approval based on objective response rate and duration

of response. Continued FDA approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The FoundationFocus™ CDxBRCA is a next generation sequencing based in vitro diagnostic device for qualitative detection of BRCA1 and BRCA2 alterations in formalin-fixed paraffin-embedded (FFPE) ovarian tumor tissue. Information on the FDA-approved test for the detection of a tumor BRCA mutation in patients with ovarian cancer is available at: http://www.fda.gov/CompanionDiagnostics. The recommended dose of Rubraca is 600 mg (two 300 mg tablets) taken orally twice daily with or without food. Continue treatment until disease progression or unacceptable toxicity.

RUBRACA™ will require a manual review PA on a case-by-case basis using the package insert data and data available in the clinical trials listed in the package insert to guide approval or denial of the request. Prescriber must provide the results of the FoundationFocus™ CDxBRCA diagnostic test, which is the FDA approved-for-selection of patients for RUBRACA™. Even though the result of this specific test, FoundationFocus™ CDxBRCA, is a requirement as part of the Prior Approval review for the drug itself, this requirement does not guarantee approval from Medicaid medical utilization review for the use of the diagnostic test nor does it guarantee payment from Medicaid for the diagnostic test. The provider must contact Medicaid medical utilization review and follow their processes for approval and/or for Medicaid payment for the diagnostic test FoundationFocus™ CDxBRCA. Prescribing provider must submit the drug PA request in writing and provide all data to substantiate the request, including but not limited to chart notes, all data on the prior use of at least two platinum-based chemotherapies, dates for prior chemotherapies, date of initial response to each prior chemotherapy, dates showing progression of disease during the course of the therapy, the treatment-free interval length of time between the therapies. Platinum-refractory patients who do not respond to platinum-based chemotherapy and show progression during the course of the platinum-based chemotherapy will not be approved for use of Rubraca. In addition, a quantity limit of 4 tablets per day will be applied to both strengths of the tablets.

Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.

2) IMPAVIDO® (miltefosine) 50 mg capsule:

Currently IMPAVIDO® is not payable in the Medicaid system because the pricing methodologies that became effective for Medicaid on 4/1/17 are not available for this drug. Should this drug become payable in the future, the prior authorization criteria below will apply. An estimation based on the previous pricing methodology is that IMPAVIDO® would be approximately $590 each capsule, and a treatment course of 50 mg twice daily x 28 days would be approximately $33,000; a treatment course of 50 mg three times daily x 28 days would be approximately $49,500.

IMPAVIDO® (miltefosine) capsules are indicated in adults and adolescents ≥12 years of age weighing ≥ 30 kg for the treatment of:

- Visceral leishmaniasis caused by Leishmania donovani;
- Cutaneous leishmaniasis caused by Leishmania braziliensis, Leishmania guyanensis, and Leishmania panamensis;
- Mucosal leishmaniasis caused by Leishmania braziliensis;

Leishmaniasis is classified as a Neglected Tropical Disease.

The dose is weight based, 30 kg – 44 kg = 50 mg twice daily with food for 28 days; ≥ 45 kg = 50 mg three time daily for 28 days.

Liposomal amphotericin B (AmBisome®), which is administered by IV infusion, is FDA-approved for treatment of visceral leishmaniasis per se (i.e., the approved indications do not include cutaneous or mucosal leishmaniasis). Conventional amphotericin B deoxycholate is also highly effective therapy for visceral leishmaniasis. One randomized, open-label, active-controlled study was conducted to evaluate the efficacy of IMPAVIDO in the treatment of visceral leishmaniasis. The active comparator was amphotericin B deoxycholate. The final cure rates for IMPAVIDO® and amphotericin B were 94% and 97%, respectively.

In addition, in the United States, special considerations apply regarding the availability of particular medications to treat leishmaniasis. Pentavalent antimonial (SbV) compounds—the traditional mainstays for treating leishmaniasis since the 1940s—are not licensed for U.S. commercial use. However, the SbV compound sodium stibogluconate (Pentostam®) is available to U.S.-licensed physicians through the CDC Drug Service (phone 404-639-3670), under an IND (Investigational New Drug) protocol approved by the Food and Drug Administration (FDA) and by CDC's Institutional Review Board. Although Pentostam® is not

new or investigational, the IND mechanism makes it possible for the CDC to stock and provide the drug in the United States. The CDC's IND protocol covers intravenous (IV) and intramuscular (IM) administration (not intralesional). In the United States, the most common route of administration is IV (vs. IM), because the volume per dose is relatively high (for example, 14 mL for a 70-kg patient).

IMPAVIDO® will require manual review prior authorization on a case-by-case basis, and may use additional information from the package insert, clinical trials, and the CDC during the review. Additionally, IMPAVIDO® must be a payable drug through the Medicaid system using one of the recognized AR Medicaid reimbursement methodologies (NADAC Generic, NADAC Brand, WAC, SAAC (aka MAC) /ACA FUL) and active in the system at the time of the PA request. Prescriber must submit request in writing with documentation of the medical necessity. Use of Pentostam® obtained through the CDC will be required for treatment of leishmaniasis as Medicaid is always the payer of last resort for a treatment. If prescriber is unable to obtain Pentostam® from the CDC, prescriber must submit documentation from CDC to support that claim. If unable to obtain Pentostam® from the CDC, then prescriber must submit documentation why amphotericin B, either the liposomal amphotericin B or the amphotericin B deoxycholate, cannot be used instead of IMPAVIDO®. Specific laboratory diagnosis is also required with the PA request; using the CDC for laboratory testing is recommended. A copy of the laboratory report is required to be submitted at the time of the PA request. If the CDC is not used for the laboratory testing, prescriber must explain why not and provide documentation. The requirement of this laboratory documentation is required as part of the manual review PA process for the drug requested but in no way guarantees payment by Medicaid of any costs incurred by or associated with the laboratory tests or for approval of IMPAVIDO®.

Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.

3) RYVENT™ (carbinoxamine maleate) tablet 6 mg

WAC for the new brand name, Ryvent 6 mg tablet = $3.9499 each tablet; (e.g., 4/day x 30 day supply = $473.99)
State MAC for the 4 mg generic carbinoxamine tablet= $0.45363 (e.g., 2 tablets 4 times a day = $108.87)

Carbinoxamine maleate is a histamine-H1 receptor blocking agent. Carbinoxamine maleate, an ethanolamine derivative, is an antihistamine with anticholinergic (drying) and sedative properties. Carbinoxamine appears to compete with histamine (type H1) for receptor sites on effector cells in the gastrointestinal tract, blood vessels and respiratory tract.

Carbinoxamine maleate is effective for the symptomatic treatment of: seasonal and perennial allergic rhinitis; vasomotor rhinitis; allergic conjunctivitis due to inhalant allergens and foods; mild, uncomplicated allergic skin manifestations of urticaria and angioedema; dermatographism; as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled; amelioration of the severity of allergic reactions to blood or plasma;

Usual adult dosage: 1 tablet (6 mg) 3 to 4 times daily.
Dosage for the 4 mg tablet states: 1 or 2 tablets (4 mg to 8 mg) 3 to 4 times daily.

RYVENT™ will require a manual review on a case-by-case basis. Prescriber must submit request in writing and provide documentation of medical necessity of receiving brand name RYVENT™ 6 mg tablet over the 4 mg generic carbinoxamine tablet or other histamine-H1 receptor blocking agents available without a PA and covered by Medicaid.

Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.

4) MIGERGOT® (ergotamine/caffeine) suppository:

WAC = $63.90 each suppository; packaged in a box of 12 rectal suppositories = $766.80

The FDA approved indication states that MIGERGOT® suppository is “indicated as therapy to abort or prevent vascular headache, e.g., migraine, migraine variants or so-called “histaminic cephalalgia”. The package insert for dosage and administration states two suppositories is the maximum dose for an individual attack and the total weekly dosage should not exceed 5 suppositories. MIGERGOT® suppositories have a long list of contraindications to drugs that are a potent CYP 3A4 inhibitors, some drugs that are less potent CYP 3A4 inhibitors, macrolide antibiotics, and pregnant women.

MIGERGOT® suppositories will require a manual review prior authorization on a case-by-case basis and prescriber must request in writing and explain the medical necessity of receiving MIGERGOT® suppositories over other treatments for vascular headache, migraine headaches, or migraine variants. The PA request review will include the beneficiary's medication history, information in the drug package insert and contraindications, and migraine treatment guidelines. Additionally, the monthly quantity edit will not exceed 12 suppositories.

Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.

5) **ILARIS® injection (canakinumab injection, powder, lyophilized, for solution) 180 mg/1.2 ml vial & 150 mg/1ml vial:**

WAC: both the 180 mg/1.2 ml vial (billing unit is per each vial) and the 150 mg/1 ml vial (billing unit is per ml) is $16,055.01 for each 1.2 ml vial or 1 ml vial.

ILARIS® was FDA approved in 2009 for Cryopyrin-Associated Periodic Syndromes (CAPS) and Systemic Juvenile Idiopathic Arthritis (SJIA). In Dec. 2016, ILARIS was approved for three additional indications:

- The treatment of Tumor Necrosis Factor (TNF) receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients;
- The treatment of Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients;
- The treatment of Familial Mediterranean Fever (FMF) in adult and pediatric patients.

The administration is subcutaneous and the dose varies by diagnosis:

- Cryopyrin-Associated Periodic Syndromes (CAPS) — ILARIS® is administered every eight weeks.
  - The recommended dose of ILARIS is 150 mg for CAPS patients with body weight greater than 40 kg. For CAPS patients with body weight greater than or equal to 15 kg and less than or equal to 40 kg, the recommended dose is 2 mg/kg. For children 15 to 40 kg with an inadequate response, the dose can be increased to 3 mg/kg.

- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency (HIDS/MKD), and Familial Mediterranean Fever (FMF) — ILARIS® is administered every 4 weeks and the recommended dose of ILARIS for TRAPS, HIDS/MKD, and FMF patients is based on body weight.
  - For patients with body weight less than or equal to 40 kg, the recommended dose is 2 mg/kg administered every 4 weeks. The dose can be increased to 4 mg/kg every 4 weeks if the clinical response is not adequate.

  - For patients with body weight greater than 40 kg, the recommended dose is 150 mg administered every 4 weeks. The dose can be increased to 300 mg every 4 weeks if the clinical response is not adequate.

- Systemic Juvenile Idiopathic Arthritis (SJIA)—ILARIS® administered every 4 weeks.
  - The recommended dose of ILARIS® for SJIA patients with a body weight greater than or equal to 7.5 kg is 4 mg/kg (with a maximum of 300 mg)

ILARIS® will require a manual review prior authorization (PA) on a case-by-case basis. Prescriber must submit request in writing and include all documentation to support the medical necessity of receiving this drug over other drug(s) that may treat the same indication. The PA request review may use FDA approved indications, dose, clinical studies, or data from the clinical studies or treatment guidelines during the review process. The approved dose will be determined during the review process.

Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.

6) **EMFLAZA™ (deflazacort) 6, 18, 30, 36 mg tablets and 22.75/ml oral suspension 13 ml:**

WAC: $245 each tablet for all strengths; $248.33384 per ml or $3,228.34 per 13 ml container for oral suspension. Example, for a 25 kg boy, the dose would calculate to be 22.5 mg. Rounded up to the nearest possible dose, = 24 mg (18 mg + 6 mg) using tablets @ 2 tablets per day, = $178,850 for 365 days; using the suspension at 1.01 ml per day = $93,621.86 for 1 year.

EMFLAZA™ is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older. The recommended oral dosage of EMFLAZA is approximately 0.9 mg/kg/day once daily. If tablets are used, round up to the nearest possible dose. Any combination of the four EMFLAZA tablet strengths can be used to achieve this dose. If the oral suspension is used, round up to the nearest tenth of a milliliter (mL). Daflazacort, at a daily dose of 0.9 mg/kg, has been shown to have a similar efficacy and side effect profile to prednisone and prednisolone.

EMFLAZA™ will require manual review prior authorization (PA) on a case-by-case basis. Prescriber must submit a letter explaining the medical necessity of receiving EMFLAZA™ over other glucocorticosteroids, such as prednisone or prednisolone, and include written documentation to substantiate the request, such as chart notes, data on all previous glucocorticosteroids tried and explanation of failure, and documentation regarding dose adjustments to other glucocorticosteroids to manage side effects. The clinical reviewers may include data obtained from the package insert, treatment guidelines, and clinical studies to assist in the review of the PA request.

Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.

7) EUCRISA™ (crisaborole) 2% ointment, 60 gm:
WAC: $9.66666 per gm; $580 for 60 gm ointment;

EUCRISA™ is indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older. Crisaborole is a phosphodiesterase 4 (PDE-4) inhibitor. PDE-4 inhibition results in increased intracellular cyclic adenosine monophosphate (cAMP) levels. The specific mechanism(s) by which crisaborole exerts its therapeutic action for the treatment of atopic dermatitis is not well defined.

Topical glucocorticosteroid agents are still first-line anti-inflammatory treatment for atopic dermatitis. The topical calcineurin inhibitors (TCIs) (tacrolimus or pimecrolimus) are 2nd line therapy and are also favored for use on certain locations on the body. The TCIs have POS prior authorization (PA) criteria in the Medicaid system and requests can also be reviewed through the manual review PA process for patients who do not meet the POS PA criteria. At this time, EUCRISA™ has not been reviewed against active comparators and is not included in current treatment guidelines for atopic dermatitis to determine its place in therapy.

EUCRISA™ will require manual review prior authorization (PA) on a case-by-case basis. Prescriber must submit a letter explaining the medical necessity of receiving EUCRISA™ and include written documentation, chart notes, and other therapies tried to substantiate the request, which should include a trial of other topical drugs to treat atopic dermatitis. Previous topical therapy should include, at a minimum, a trial of at least two different topical corticosteroids over a minimum of 60 days use with at least one topical corticosteroid being "medium" potency or higher, and the use of at least one TCI over a minimum of 30 days. The clinical reviewers may include data obtained from the package insert, treatment guidelines, and clinical studies to assist in the review of the PA request.

Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.

EFFECTIVE JUNE 29, 2017

D. NEW CLAIM EDITS, INCLUDING DOSE-OPTIMAZATION EDITS, DAILY DOSE/QUANTITY EDITS, CUMULATIVE QUANTITY EDIT, And ACCUMULATION QUANTITY EDITS

1) LIDOCAINE 5% OINTMENT in 30 gm, 35 gm, and 60 gm tubes:
NADAC Generic rate ranges from $52.09 to $131.88 per tube.

A QUANTITY LIMIT for LIDOCAINE 5% OINTMENT has been implemented that will allow for *one package size of the NDC* (e.g., one 35.44 gm tube, one 30 gm tube, *or* one 50 gm tube), whether dispensed as a compounded prescription or dispensed as LIDOCAINE 5% OINTMENT. In addition, therapeutic duplication edits have been implemented that will *not* allow using more than one NDC for concurrent therapy with overlapping days' supply or in a compounded product. The LIDOCAINE 5% OINTMENT package insert contains a warning that states "*excessive dosage or short intervals between doses can result in high plasma levels and serious adverse effects*". Quantities greater than one package size of the NDC will require manual review prior approval and will require the prescriber to fax to Medicaid a letter explaining the medical

necessity of the larger quantity, frequency of administration, length of therapy, and the body surface area being treated in order for the request to be reviewed.

Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.

2) Anthelmintic Drugs: Biltricide® (praziquantel) 600 mg tablet; Albenza® (albendazole) 200 mg tablet, Stromectol® (ivermectin) 3 mg tablet:

NADAC Brand for BILTRICIDE® 600 mg tablet = $81.78745 *each tablet*.
NADAC Brand for ALBENZA® 200 mg tablet= $160.795 *each tablet*; 4 tablets = $643.18.
WAC for brand name STROMECTOL® 200 mg tablet = $4.6525 *each tablet*;
NADAC Generic for ivermectin = $3.90225 *each tablet*.

The use of BILTRICIDE® (praziquantel), ALBENZA® (albendazole), or STROMECTOL® (ivermectin) tablets for treating the common intestinal parasites are off-label uses. The common intestinal parasites include pinworm (enterobiasis), hookworm, common roundworm (ascariasis), whipworm, tapeworm, roundworm strongyloides, which is most commonly found in topical or subtropical climates, or roundworm toxocara, which is caused by roundworm eggs accidently ingested from infected dogs and cats. However, the CDC does provide dose information for these common intestinal parasites when the drug is effective for the specific parasite. Dosing information from the CDC is listed below.

BILTRICIDE® 600 MG TABLET-- One 600 mg tablet will treat a 60-kg person at 10 mg/kg. For TAPEWORM infection (Taeniasis), weight-based dose is 5-10 mg/kg in adults or children, given orally as a single dose. Off-label uses for pinworm, hookworm, *Ascaria, Strongyloides, Toxocara*, and whipworm are not FDA approved and do *not* have dosing information provided by CDC.

ALBENZA® 200 MG TABLET--- The CDC states the safety of albendazole in children less than 6 years old is not certain. Children less than 6 years old have been treated according to World Health Organization (WHO) guidelines at a reduced dose. For PINWORM infection, given orally as a single dose (2 tablets once), repeat dose (2 tablets) 2 weeks later. For HOOKWORM infection, ≥ 2 years of age, 400 mg daily for 3 days. For ASCARIASIS infection ("common" roundworm infection caused by *Ascaris*), 400 mg orally given as a single oral dose. STRONGYLOIDIASIS (roundworm infection caused by *Strongyloides stercoralis*), ALBENZA® is 2nd line or alternative therapy at 400 mg twice daily x 7 days. For TOXOCAR, (roundworm caused from cats and dogs), the dose is 400 mg twice daily for 5 days. WHIPWORM infection, the dose is 400 mg once daily for 3 days.

STROMECTOL® (ivermectin) 200 MG TABLET—Ivermectin uses a weight based dose. Per the CDC, the safety of ivermectin in children who weigh less than 15kg has not been demonstrated. According to the WHO guidelines for mass prevention campaigns, children who are at least 90 cm tall can be treated safely with ivermectin. For Taeniasis (infection caused by HOOKWORM), and for ASCARIASIS, ("common" roundworm infection caused by *Ascaris*), 150-200 mcg/kg given as a single oral dose. For STRONGYLOIDIASIS (roundworm infection caused by *Strongyloides stercoralis*), ivermectin is first line treatment using dose of 200 mcg/kg given as a single dose for 1 to 2 days. For WHIPWORM, 200 mcg/kg for 3 days. For "classic scabies" for patients who have failed treatment with or who cannot tolerate FDA-approved topical medications for the treatment of scabies, dose is 200 mcg/kg given as 2 doses one week apart. For "crusted scabies" administer together with a topical agent, dose is 200 mcg/kg and depending on infection severity, ivermectin should be taken in three doses (approximately days 1, 2, and 8), five doses (approximately days 1, 2, 8, 9, and 15), or seven doses (approximately days 1, 2, 8, 9, 15, 22, and 29). The ivermectin dosing chart for all indications is included below.

Ivermectin weight-based dose	
Body Weight (kg)	**Single Oral Dose**
	Number of 3-mg Tablets
15-24	1 tablet
25-35	2 tablets
36-50	3 tablets
51-65	4 tablets
66-79	5 tablets
≥80	200 mcg/kg

QUANTITY LIMITS for ALBENZA® and BILTRICIDE® have been implemented as stated below. Only medications prescribed to the Medicaid beneficiary can be billed using the beneficiary's Medicaid ID. *The quantity billed to Medicaid cannot exceed the quantity prescribed by the prescribing provider for that beneficiary—any quantity billed to Medicaid that exceeds the quantity prescribed to the beneficiary will be recouped.* If medications are needed to treat remaining family members, each prescription must be billed

accordingly to each family member's Medicaid ID number. If a larger quantity is required than what is allowed by the quantity edits, the prescriber must submit the request in writing, provide the beneficiary's weight, and provide the diagnosis being treated in order for the request to be reviewed. *Utilization of these agents will continue to be monitored.*

- ALBENZA® (albendazole) 200 mg tablet --- quantity limit of up to a quantity of 4 tablets.
- BILTRICIDE® (praziquantel) 600 mg tablet --- a quantity limit of 1 tablet.
- EMVERM™ (mebendazole) 100 mg chew tablet -- No change; Manual Review PA for mebendazole 100 mg tablet, and the quantity limit remains at 1 tablet.
- STROMECTOL® (ivermectin) 3 mg tablet --- no quantity edit has been set at this time.

Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.

3) <u>CYCLOBENZAPRINE TABLETS</u>:
Cyclobenzaprine 10 mg tablet is listed as preferred status in the skeletal muscle relaxant category on the PDL; the cyclobenzaprine 5 mg and 7.5 mg tablets are non-preferred status. The dose as stated in the package insert is "5 mg three times a day. Based on individual patient response, the dose may be increased to either 7.5 mg or 10 mg three times a day". Less frequent dosing should be considered for hepatically impaired or elderly patients. Use of cyclobenzaprine HCl for periods longer than two or three weeks is not recommended. Although rare, deaths may occur from overdosage with cyclobenzaprine HCl. Multiple drug ingestion (including alcohol) is common in deliberate cyclobenzaprine overdose. The most common effects associated with cyclobenzaprine overdose are drowsiness and tachycardia. Less frequent manifestations include tremor, agitation, coma, ataxia, hypertension, slurred speech, confusion, dizziness, nausea, vomiting, and hallucinations. Rare but potentially critical manifestations of overdose are cardiac arrest, chest pain, cardiac dysrhythmias, severe hypotension, seizures, and neuroleptic malignant syndrome.

A QUANTITY LIMIT has been implemented for each strength of cyclobenzaprine tablets to not exceed 3 tablets per day and a maximum of 93 tablets for a 31 days' supply.

PDL PA Call Center 1-800-424-7895; t**he PDL FAX number is 1-800-424-5739.**

FRIENDLY REMINDERS:

1. **<u>CHANGE IN MANUAL REVIEW PA FOR THE AGE OF CHILDREN PRESCRIBED ANTIPSYCHOTIC AGENTS, EFFECTIVE JANUARY 1, 2017</u>:** Medicaid currently requires a manual review PA of any antipsychotic agent prescribed for children less than 10 years of age (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.** This manual review is performed by the Medicaid Pharmacy Program board certified child & adolescent psychiatrist. All documentation, chart notes, signed informed consent, and required lab work must be submitted and will be reviewed by the Medicaid Pharmacy Program child & adolescent psychiatrist.

2. **<u>SECOND GENERATION ANTIDEPRESSANTS, TRAZODONE, AND TRICYCLIC ANTIDEPRESSANTS PRESCRIBED TO CHILDREN ≤ 3 YEARS OF AGE, *EFFECTIVE MARCH 8, 2017*</u>:** The current point of sale (POS) prior approval (PA) criteria for the second generation antidepressants, including Trazodone, were developed based on utilization for adults, and the minimum and maximum therapeutic doses were based on adult doses. ***Second Generation Antidepressants, Trazodone, or Tricyclic Antidepressants for Children ≤ 3 years of age will require manual review prior approval (PA) by the Medicaid Pharmacy Program child psychiatrist.*** The prescriber must submit the request in writing, explain the medical necessity for the child to receive the drug requested, and include chart notes and any other documentation that will substantiate the request and the dose. Each request will be reviewed on a case-by-case basis.

3. **<u>REGARDING EMERGENCY OVERRIDE</u>**: 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 situation</u> when the MMA Prescription Drug 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. Frequency of the emergency override is limited to once per year per drug class or drug category for non-LTC-eligible beneficiaries and once per 60 days per class for LTC-eligible beneficiaries. 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://arkansas.magellanrx.com/provider/documents/.

4. **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 a Medicaid beneficiaries who, ***on the date the prescription is filled, 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.

5. **HARD EDIT ON EARLY REFILL FOR CONTROLLED AND 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. 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.

6. **REFILL TOO SOON ACCUMULATION LOGIC:** Beginning February 16, 2016, when a pharmacy refills a prescription claim early (e.g., for a non-controlled drug or a controlled drug 1 day early to 7 days early without a PA or sooner with a PA), 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. Once the beneficiary has accumulated an "extra" 15 days' supply for that GSN, any incoming claim that is early will reject at point of sale. For example, if the prescription drug claim was for a 30-day supply and was filled 7 days early on February 16, 2016, and filled 7 days early again on March 10, 2016, the beneficiary can only refill the prescription 1 day early on the next refill date, which would be April 8, 2016 (1 day early). The accumulation edit is set so that the beneficiary cannot accumulate *more than* an *extra* 15 days' supply early during a 180-day period. In this example, the drug claim cannot be filled early again until *after* August 14, 2016, which is 180 days from the February 16, 2016 date. The limits for the "Refill Too Soon Accumulation Logic" are currently the same for non-controlled drugs and controlled drugs, including opioids. Early refills for both controlled drugs and non-controlled drugs will continue to be monitored and may be adjusted in the future to reduce misuse.

7. **REVERSE AND CREDIT MEDICAID PRESCRIPTIONS NOT PROVIDED TO BENEFICIARY:** 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.

8. **ANTIPSYCHOTIC AGENTS CRITERIA FOR CHILDREN < 18 YEARS OF AGE have an ongoing requirement for labs** for metabolic monitoring. When any provider sends a patient who is less than 18 years of age for the metabolic labs that are required for the antipsychotic agents, 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.

9. **INFORMED CONSENT FORM FOR ANTIPSYCHOTIC AGENT PA FOR CHILDREN < 18 YEARS OF AGE:**
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 has been updated (v072914) and is posted on the Medicaid website. As the form is updated and posted on the Medicaid website, providers are required to use the most current form. Effective, Dec. 10, 2013, the old versions will no longer be accepted.

10. **FOR PDL REQUESTS AND FOR REQUESTS FOR ANTIPSYCHOTIC DRUGS: Effective JULY 1, 2016**, Providers requesting a Prior Authorization (PA) for a drug on the PDL or calling to request a Prior Authorization (PA) for an antipsychotic medication should call the **PDL PA Call Center at 1-800-424-7895**. **The PDL FAX number is: 1-800- 424-5739**. Please fax a letter explaining the medical necessity and include any supporting documentation, the beneficiary ID number, beneficiary name, and Medicaid Provider ID with your request.

11. **FOR NON-PDL DRUGS AND FOR NON-ANTIPYSCHOTIC DRUG REQUESTS:** Providers requesting a Prior Authorization (PA) should call the Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895. For Prior Authorization (PA) requests requiring manual review, you may fax your request to the MMA Help Desk Fax at 1-800-424-7976. Please include any supporting documentation for the request with the fax, and include beneficiary ID number, beneficiary name, and physician Medicaid provider ID with your request. An approval, denial, or request for additional information will be returned by the close of business the following business day.

12. **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 accordingly 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.

13. **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://arkansas.magellanrx.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://arkansas.magellanrx.com/client/docs/rxinfo/ARRx_NADAC_Request_Medicaid_Reimbursement_Review_Form.pdf

14. **AR MEDICAID PHARMACY PROGRAM IS ON FACEBOOK:** The Arkansas Medicaid Pharmacy Program is now on Facebook. Please join our group page titled "AR Medicaid Pharmacy Provider Help Group". This is a closed group for providers of Arkansas Medicaid services or those who work for a provider of Arkansas Medicaid services and join requests will be verified. The group is administered by a State of Arkansas employee and a Magellan Medicaid Administration employee on his/her own time. The purpose of the group page is to help the provider community with any issues that involve billing or prescribing covered outpatient drugs through the Arkansas Medicaid Pharmacy Program. We will not disclose any PHI and will delete any posts that contain PHI. Want to know what criteria is needed for a drug? Don't know who to call to handle your issue? Just post your questions and we will answer.

This advance notice is to provide you 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 Magellan Medicaid Administration (MMA) 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 HP Enterprise Services Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at 1-501-376-2211.