



Division of Medical Services
Pharmacy Program



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MEMORANDUM

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

FROM: Cynthia Neuhofer, Pharm.D. Division of Medical Services Pharmacy Program

Cynthia Neuhofer

DATE: August 28, 2019

SUBJ: AR Medicaid Prior Authorization Edits Approved at the AR Medicaid DUR Board July 17, 2019 meeting for the following: Manual review criteria for NUZYRA® (omadacycline) for injection and oral tablets; ABILIFY MYCITE® (aripiprazole) tablets; FIRDAPSE®/RUZURGI (amifampridine) tablets; BALVERSA™ (erdafitinib) tablets; ALPHA-1 PROTEINASE INHIBITORS; HEPATITIS C VIRUS TREATMENT IN PEDIATRICS; TIBSOVO® (ivosidenib) tablets; VYNDAQEL®/VYNDAMAX™ (tafamidis meglumine/tafamidis) capsules; TARCEVA® (erlotinib) tablets AND EVENITY™ (romosozumab-aqqg) injection. Update on current criteria for EMFLAZA® (deflazacort) tablets; PROTON PUMP INHIBITORS; OSTEOPOROSIS TREATMENT AND NEW MEDICATION-ASSISTED TREATMENT FORMS.

Preferred Drug List (PDL) Drugs from the August 14, 2019 Drug Review Committee Meeting for the following: Inhaled antibiotics; CGRP-receptor blockers for migraine; bone resorption suppression and related agents; growth hormones; otic anti-infectives and anesthetics; otic antibiotics, pancreatic enzymes and head lice agents.

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ANNOUNCEMENTS

1) REMINDER: Morphine Milligram Equivalents (MME) Final Reduction

The final MME was reduced to **≤90 MME/day** on **November 14, 2018**. This is an additive edit for all opioid drug claims with overlapping days' supply. The beneficiaries with certain cancer diagnoses in Medicaid medical diagnosis history are exempted from the MME edit. Incoming opioid claims that cause the total MME/day to exceed the existing limit of **≤ 90 MME/day** will *deny at point of sale* whether prescription is from same prescriber or different prescriber(s).

2) ELECTRONIC PROVIDER MEMO:

To reduce paper waste beginning April 2019, Arkansas Medicaid will no longer mail Pharmacy Program Provider Memos. An electronic message will be sent to all Medicaid enrolled prescribing providers and pharmacy providers as an alert message when the complete Provider Memo is posted on the Arkansas Medicaid Pharmacy Program website.

NOTE: To ensure you receive the notification email, please verify that your email is correct in the Arkansas Medicaid provider portal. Department of Human Services correspondence would also be included in this effort to reduce paper waste. To ensure that all correspondence is received, we ask that each provider verify that the provider portal has the correct email address used for your business communications.

The Arkansas Medicaid Pharmacy Program Provider Memos can be found at <https://medicaid.mmis.arkansas.gov/Provider/Provider.aspx>. To access the memos, select the OTHER LINKS drop-down menu in the upper-left corner of the screen, click MAGELLAN MEDICAID ADMINISTRATION, select the Administrator box, select the RESOURCES drop-down menu in the upper-right corner, click Documents, select the PHARMACY tab in the top row of tabs, and then click MEMORANDUMS. The Memo can also be found at: <https://arkansas.magellanrx.com/provider/documents/>. To access the memos, select the Pharmacy tab and then click Memorandums.

An added benefit of viewing the Medicaid Pharmacy Program Provider Memo online is the Search feature, which will allow a more accessible and efficient user experience. To use this feature, use the shortcut by pressing the Ctrl + F keys, enabling a keyword search. Starting with the January 2018 memo, the online versions of the Provider Memos will also contain active hyperlinks in the Table of Contents. To activate these hyperlinks, open the Provider Memo, hover the mouse over the Table of Contents, press the Ctrl key until the mouse cursor ("hand") appears, then place the cursor on the item desired and click

the mouse. The hyperlink in the Table of Content will then redirect to the corresponding chapter of the Provider Memo.

3) EXTRA ALBUTEROL HFA INHALER FOR MONTH OF AUGUST

For the month of August 2019, recipients under the age of 18 will be allowed up to 3 Albuterol HFA inhalers with an approved override. ProAir HFA and Proventil HFA are the preferred products. If an override is needed, please call the Magellan Help Desk at 1-800-424-7895.

4) GLEEVEC (brand name) 100MG CAPSULES

Effective 9/15/2019, brand name Gleevec 100mg capsules will no longer be preferred. **IMATINIB 100MG AND 400MG CAPSULES WILL BE THE PREFERRED.** As of 9/15/2019, to ensure pharmacy claims are reimbursed correctly, the imatinib generic must be dispensed.

EFFECTIVE October 1, 2019:

PREFERRED DRUGS LIST (PDL):

Oral antipsychotic agents were reviewed at the May 8, 2019 PDL meeting. The implementation of oral antipsychotic agents on the PDL was delayed ensuring proper processing with the previous clinical edits approved during the April 2019 DUR meeting. The following classes were reviewed during the August 14, 2019 PDL meeting: growth hormones, osteoporosis agents, inhaled antibiotics, otic anti-infective and anesthetics, otic antibiotics, anti-migraine medications (CGRP receptor blockers), pancreatic enzymes and topical head lice treatments. The preferred status and non-preferred status drugs were selected based on a review of comparative effectiveness as well as cost-effectiveness for the state Medicaid program and are listed below. *Prior Authorization criteria* and quantity limits will remain in place for Preferred-status drugs unless otherwise noted below. Agents in **bold** font indicate a change in designation on the PDL.

ANTIPSYCHOTICS (from the May 2019 DRC meeting)

PREFERRED

Amitriptyline/Perphenazine tablets
Aripiprazole Tablets
Clozapine Tablets
Fluphenazine Tablets
Haloperidol Lactate Conc Solution
Haloperidol Tablets
Loxapine Capsules
Olanzapine Tablets and ODT
Perphenazine Tablets
Pimozide Tablets
Quetiapine Tablets
Risperidone Tablets, Solution, and ODT
Thioridazine Tablets
Thiothixene Capsules
Trifluoperazine Tablets
Ziprasidone Capsules

NON-PREFERRED

Abilify Mycite tablets
Abilify Tablets (Brand Name)
Aripiprazole Solution and ODT (Generic)

Chlorpromazine Tablets (Brand and Generic)

Clozaril Tablets (Brand Name)
Etrafon Tablets (Brand Name)
Fanapt Tablets
Fazacllo ODT/Clozapine ODT/Versacloz
Fluphenazine Elixir/Solution
Geodon capsules (Brand Name)
Haldol Lactate Conc Solution (Brand Name)
Haldol Tablets (Brand Name)
Latuda Tablets
Loxitane Capsules (Brand Name)
Mellaril Tablets (Brand Name)
Molindone Tablets (Brand and Generic)
Navane Capsules (Brand Name)
Nuplazid Tablets (requires manual review)
Orap Tablets (Brand Name)

Paliperidone Tablets (Brand and Generic)

Prolixin Tablets (Brand Name)
Rexulti Tablets
Risperdal tablets, Solution, and ODT (Brand name)
Saphris Sublingual
Seroquel tablets (Brand name)
Stelazine Tablets (Brand Name)
Trilafon Tablets (Brand Name)
Vraylar Capsules
Zyprexa tablets and ODT (Brand Name)
Zyprexa Zydis

August 2019 DRC meeting

INHALED ANTIBIOTICS

PREFERRED

Tobramycin (AG and Generic only)

NON-PREFERRED

Kitabis®

Bethkis™

TOBI®

TOBI Podhaler®

Cayston®

Arikayce® (requires manual review)

CGRP ANTAGONISTS

PREFERRED

Emgality® 120mg syringe and pen

NON-PREFERRED

Emgality® 100mg syringe

Aimovig® Autoinjector (all strengths)

Ajovy® 225mg syringe

OSTEOPOROSIS

PREFERRED

Alendronate tablet (all strengths of generic only)

NON-PREFERRED WITH CRITERIA

Raloxifene (Evista®) tablet

Prolia® injection

NON-PREFERRED NO CRITERIA

Atelvia® (risedronate) tablet

Ibandronate (Boniva®) tablet and injection

Risedronate (Actonel®) tablet

Binosto® (alendronate effervescent) tablet

Forteo®

Tymlos®

Evenity® (requires manual review)

Etidronate tablet

Calcitonin-Salmon (Fortical® and Miacalcin®) nasal spray (requires manual review)

GROWTH HORMONE

PREFERRED WITH CRITERIA

Genotropin®

NON-PREFERRED

Humatrope®

Norditropin®

Nutropin AQ® NuSpin®

Omnitrope®

Zomacton™

Saizen®

Zorbtive®

OTIC ANTI-INFECTIVES

PREFERRED

Acetic acid otic

Ofloxacin otic

Ciprodex® (ciprofloxacin and dexamethasone suspension)

Neomycin/Polymyxin/HC otic solution

NON-PREFERRED

Cipro® HC Otic

Coly-Mycin® S otic

Ciprofloxacin otic

Otovel® otic (ciprofloxacin and fluocinolone acetonide)

Cortisporin® TC

Otiprio® otic (ciprofloxacin)

PANCREATIC ENZYMES

PREFERRED

Zenpep®

Creon®

NON-PREFERRED

Viokace®
Pancreaze®
Pertzye®

TOPICAL ANTIPARASITICS (HEAD LICE TREATMENT)

PREFERRED

Permethrin 1% OTC
Permethrin 5% (Elimite™)
Piperonyl butoxide 4%/pyrethrum extract 0.33% OTC
Natroba™ (Spinosad) BRAND NAME ONLY

NON-PREFERRED

Ulesfia® (benzyl alcohol 5%)
Sklice® (ivermectin 0.05%)
Eurax cream and lotion (crotamiton 10%)
Ovide® (malathion 0.05%)
Spinosad 0.9% **GENERIC**

PRIOR AUTHORIZATION DRUG CRITERIA, NEW OR REVISED, FOR THE FOLLOWING DRUGS:

1) MEDICATION-ASSISTED TREATMENT (MAT) FORMS

New Medication-Assisted Treatment (MAT) forms were effective 7/1/19 for buprenorphine containing products and Vivitrol®. Vivitrol® can now be billed as a pharmacy claim or a medical claim effective 7/1/19 and would be manually reviewed on a case-by-case basis with previously approved criteria.



MAT PA Form
Vivitrol 062719 - FIN



MAT PA Form Bup
Vivitrol 062719 - FIN Products 062719 - FI

EFFECTIVE IMMEDIATELY:

2) EMFLAZA® (deflazacort) 6mg, 16mg, 30mg and 36mg tablets

EMFLAZA® (deflazacort) will continue to require manual review PA on a case-by-case basis and will use all of the following:

APPROVAL CRITERIA and information needed:

- Beneficiary has a confirmed genetic diagnosis of Duchenne muscular dystrophy (DMD);
- Age ≥ 2 years old
- Provide documentation of the mutation in the dystrophin gene;
- Prescribed by a provider who specializes in the treatment of DMD and/or neuromuscular disorders;
- Provide a letter of medical necessity with a significant reason specific to the beneficiary that EMFLAZA® is needed over other glucocorticosteroids, such as prednisone or prednisolone;
- Prescriber must submit documentation to substantiate the medical necessity request of EMFLAZA® over other glucocorticoid agents, including submitting chart notes, data on all previous glucocorticosteroid(s) tried, and include explanation of failure or explanation of an adverse effect caused by prednisone or prednisolone that is not also caused by EMFLAZA®;
- Provide documentation of current weight and dosage requested;

- Provide documentation that beneficiary has received a baseline eye examination;
- Provide documentation that the beneficiary is currently receiving, or planning to receive, physical therapy and provide physical therapy notes;
- Provide documentation of Child-Pugh Score (no clinical experience in patients with severe hepatic impairment)

DENIAL CRITERIA:

- Beneficiary is < 2 years of age;
- Beneficiary does not meet above approval criteria;
- Beneficiary has not received prednisone or prednisolone;
- Beneficiary did not receive the weight-based dose on a daily schedule of prednisone or prednisolone (0.75 mg/kg/day);
- Beneficiary is classified as Child Pugh C

CONTINUATION CRITERIA:

- Beneficiary continues to receive physical therapy;
- Provide current chart notes and physical therapy notes;
- Provide current weight and dosage requested;
- Provide documentation of yearly eye examinations;
- Beneficiary is adherent to the prescribed dose of EMFLAZA®

3) PROTON PUMP INHIBITORS

Due to the concern of possible long-term effects of PPI usage, this class of drugs was re-reviewed by the DUR Board.

UTILIZATION of PPIs for Arkansas Medicaid recipients:

July 2018-March 2019

Total claims= 43,835 (avg. 4,871 per month)

Total Recipients= 18,693

Magellan Help Desk receives approximately 1000 prior authorization requests per quarter for PPIs. Most PA requests were due to the recipient exceeding a 93-day supply in 365 days.

In comparison with H2-receptor inhibitors:

Total claims=56,284 (avg. 6,254 per month)

Total recipients=22,858

CURRENT APPROVAL CRITERIA FOR PREFERRED AGENTS WITH CRITERIA:

- Approve up to 93 days of proton pump inhibitor therapy per year for all recipients age 15 months and older;
- Approve treatment beyond 93 days for recipients 15 months or older who have a diagnosis in history for Zollinger-Ellison Syndrome, Barrett's esophagus, esophageal varices, or an endoscopy in the past 24 months
- Approve treatment beyond 93 days for recipients 15 months or older who have a diagnosis in history for Cystic Fibrosis, pancreatic insufficiency, or pancreatic disease in the past 24 months

LIFESTYLE AND HOME REMEDIES:

Lifestyle changes may help reduce the frequency of acid reflux. Try to:

- Maintain a healthy weight
- Stop smoking
- Elevate the head of your bed
- Don't lie down after a meal

- Eat food slowly and chew thoroughly
- Avoid foods and drinks that trigger reflux
- Avoid tight-fitting clothing
- Herbal remedies
- Relaxation therapies

The DUR Board decided there should be no changes to the current approval criteria. The Board did want to bring more attention to the overuse of PPIs and potential long-term effects. Also they ask providers to consider H2-receptor antagonists and lifestyle changes when possible. In addition to the current criteria, Retrospective Drug Utilization Review will be added in an attempt to help monitor PPI usage.

EFFECTIVE IMMEDIATELY:

4) EVENTITY™ (romosozumab-aqgg) 105mg injection

EVENTITY is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

The anabolic effect of EVENTITY™ wanes after 12 monthly doses of therapy. Therefore, the duration of EVENTITY™ use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.

EVENTITY™ inhibits the action of sclerostin, a regulatory factor in bone metabolism. EVENTITY™ increases bone formation and, to a lesser extent, decreases bone resorption.

RECOMMENDED DOSAGE

- The recommended dose of EVENTITY™ is 210 mg administered subcutaneously in the abdomen, thigh or upper arm. Administer EVENTITY™ once every month.
- The treatment duration for EVENTITY™ is 12 monthly doses.
- Patients should be adequately supplemented with calcium and vitamin D during treatment with EVENTITY™.
- If the EVENTITY™ dose is missed, administer as soon as it can be rescheduled. Thereafter, EVENTITY™ can be scheduled every month from the date of the last dose.

▲ DENOTES PULLED FROM CLINICAL TRIAL NCT01575834

APPROVAL CRITERIA and information needed:

- Manual review on a case-by-case basis;
- Age ≥ 55 years old ▲;
- Provide baseline calcium and vitamin D levels;
- Must be postmenopausal;
- Bone marrow density score at the hip or femoral neck of ≤ -2.50 ▲;
- Documentation that patient is at high risk for fracture (osteoporotic fracture or multiple risk factors) or has failed or intolerant to therapy available without a PA;
- Chart notes and documentation of previously tried medications;
- PA could be approved for up to 6 months per review (max of 12 months total)

DENIAL CRITERIA:

- Myocardial infarction or stroke within the preceding year;
- Uncontrolled hypocalcemia;
- No documentation of current calcium and vitamin D usage;
- No medical necessity was established over the medications available without a PA

CONTINUATION CRITERIA:

- Maximum treatment duration is 12 months;
- If not compliant on Evenity™ and not taking anti-resorptive medication, continuation would require documentation of medical necessity

QUANTITY EDITS:

2 syringes = 1 dose; 2 syringes per 30 days; maximum of 1 year

EFFECTIVE October 1, 2019:

5) OSTEOPOROSIS AGENTS

RECOMMENDATIONS FOR THE WHOLE CLASS: Refill too soon and accumulation edits will apply to all medications.

SEE THE ABOVE PREFERRED DRUG LIST WHEN REVIEWING CRITERIA BELOW.

1) Bisphosphonates

- a. For postmenopausal women at high risk for fractures with fracture risk reassessed after 3-5 years.
- b. The preferred bisphosphonates will be available without a PA. The non-preferred bisphosphonates will require documentation of medical necessity faxed for review.
- c. Quantity edits
 - i. Alendronate 5mg & 10mg--#30 per 30 days; Alendronate 35mg and Alendronate 70mg--#4 per 28 days (Fosamax®)
 - ii. Risedronate 5mg and 30mg--#30 per 30 days; Risedronate 35mg--#4 per 28 days; Risedronate 75mg--#2 per 38 days; Risedronate 150mg--#1 per 28 days (Actonel®)
 - iii. Risedronate DR 35mg--#4 per 28 days (Atelvia®)
 - iv. Alendronate effervescent 70mg--#4 per 28 days (Binosto®)
 - v. Ibandronate 150mg--#1 per 28 days (Boniva®)
 - vi. Ibandronate 3mg injection--#1 per 84 days
 - vii. Fosamax Plus D® 70mg/2800mg--#4 per 28 days; Fosamax Plus D® 70mg/5600mg--#4 per 28 days
 - viii. Alendronate oral solution—300ml per 28 days (four 75ml bottles) (Fosamax®)

2) Prolia® (denosumab) injection

- a. For postmenopausal women at high risk for osteoporotic fractures; Reassess after 5-10 years
- b. Consider when alternative initial treatment of bisphosphonates is not an option
- c. Current criteria—

Prolia® will continue to be covered through a manual review PA on a case-by-case basis for the initial dose. POS PA continuation approval criteria for Prolia® will apply as follows:

 - i. 1 Prolia® claim is found in Medicaid drug history in the previous 12 months.
 - ii. In addition, a therapeutic duplication edit will reject an incoming Prolia® claim if an Xgeva® (denosumab) claim is found in the medical claims history in previous 6 months.
- d. No change to the above current criteria; manual review on initial request with continuation criteria once approved
- e. Quantity edits--#1 per 175 days

3) Forteo® (teriparatide) injection AND Tymlos® (abaloparatide) injection

- a. For postmenopausal women with osteoporosis at very high risk of fracture, such as those with severe or multiple vertebral fractures.
- b. Indicated for only 2 years of therapy; when stopped, should start anti-resorptive agent
- c. Manual review—medical necessity over denosumab and bisphosphonates
- d. Quantity edits
 - i. Forteo®--2.4ml per 28 days (max of 24 claims)
 - ii. Tymlos®--1.6ml per 28 days (max of 24 claims)

4) Evista® (raloxifene) AND Duavee® (bazedoxifene)

- a. For postmenopausal women with osteoporosis at high risk of fracture with low risk of DVT.
- b. Bisphosphonate and denosumab are not appropriate or has a high risk of breast cancer
- c. No change in criteria; same point-of-sale criteria
Diagnosis of post-menopause in the previous 2 years, AND
 - o Diagnosis of carcinoma in situ of breast in the previous 2 years, OR
 - o Diagnosis of atypical hyperplasia of breast in the previous 2 years, OR
 - o Diagnosis of Family History of Malignant Neoplasm of Breast in previous 2 years;OR
 - Diagnosis of post-menopause in the previous 2 years, AND
 - Diagnosis of osteoporosis in the previous 2 years, AND
 - o Diagnosis of esophageal strictures in the previous 2 years , OR
 - o Diagnosis of esophageal achalasia in the previous 2 years
- d. Quantity edits--#30 per 30 days

5) Evenity™ (romosozumab-aqqg) injection

- a. For postmenopausal women at high risk for fracture, denied as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients have failed or are intolerant to other available osteoporosis therapy.
- b. Manual review—medical necessity over preferred alternatives
- c. Quantity edits—2 syringes (1 dose) per 30 days (max of 12 claims)

6) Miacalcin® (calcitonin salmon) or Fortical® (calcitonin) nasal spray

- a. For postmenopausal women at high risk of fracture with osteoporosis who cannot tolerate raloxifene, bisphosphonates, estrogen, denosumab, abaloparatide, or teriparatide
- b. Change from point-of-sale criteria to manual review; medical necessity over all other alternatives is required per the 2019 Endocrine guidelines
- c. Miacalcin® and Fortical® require women to be greater than 5 years postmenopausal
- d. Quantity edits
 - i. Injection—16ml (8 vials) per 30 days
 - ii. Nasal spray—3.7ml (1 bottle) per 30 days

EFFECTIVE IMMEDIATELY:

6) NUZYRA® (omadacycline) 100mg injection and 150mg oral tablets

NUZYRA® is a tetracycline class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

- o Community-acquired bacterial pneumonia (CABP)
- o Acute bacterial skin and skin structure infections (ABSSSI)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of NUZYRA® and other antibacterial drugs, NUZYRA® should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Table 1: Dosage of NUZYRA in Adult CABP Patients		
Loading Doses	Maintenance Dose	Treatment Duration
200 mg by intravenous infusion over 60 minutes on day 1. OR 100 mg by intravenous infusion over 30 minutes, twice on day 1.	100 mg by intravenous infusion over 30 minutes once daily. OR 300 mg orally once daily.	7 to 14 days

Table 2: Dosage of NUZYRA in Adult ABSSSI Patients		
Loading Doses	Maintenance Dose	Treatment Duration
200 mg by intravenous infusion over 60 minutes on day 1. OR 100 mg by intravenous infusion over 30 minutes, twice on day 1.	100 mg by intravenous infusion over 30 minutes once daily. OR 300 mg orally once daily.	7 to 14 Days
450 mg orally once a day on day 1 and day 2.	300 mg orally once daily	

▲ DENOTES PULLED FROM CLINICAL TRIAL NCT02531438, NCT02378480 OR NCT02877927.

NUZYRA® tablet and vials for injection will require manual review PA on a case-by-case basis using all of the following:

APPROVAL CRITERIA:

- Beneficiary is \geq 18 years old;
- Beneficiary has a diagnosis of:
 - **Community-Acquired Bacterial Pneumonia (CABP)**
 - **Acute Bacterial Skin and Skin Structure Infections (ABSSSI)**
- Prescriber should provide culture and susceptibility report if available;
- Prescriber must provide explanation of medical necessity for use of this antibiotic over a different agent that does not require prior authorization;
- Prescriber must submit documentation of loading dose of IV infusion or loading dose of oral tablets beneficiary received for the diagnosis and submit planned length of therapy;
- Negative pregnancy test

DENIAL CRITERIA:

- No diagnosis of CABP or ABSSSI with an organism listed in the approval criteria;
- Age \leq 18 years old;
- Tetracycline allergy;

- Susceptibility report shows organism is resistant ;
- Female beneficiary is in 2nd or 3rd trimester of pregnancy or breastfeeding;
- Known or suspected healthcare associated infection;
- Request is for greater than 14 days of therapy

CONTINUATION CRITERIA:

- PA approval will not be extended beyond 14-day course of treatment

QUANTITY LIMIT:

- Quantity limit for either tablets or vials for length of therapy (7 to 14 days) will be entered at the time of the PA approval;
- Length of therapy will not exceed 14 days

EFFECTIVE IMMEDIATELY:

7) ABILIFY MYCITE® (aripiprazole) 2mg, 5mg, 10mg, 15mg, 20mg and 30mg tablets

ABILIFY MYCITE®, a drug-device combination product comprised of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor intended to track drug ingestion, is indicated for the:

- Treatment of adults with schizophrenia
- Treatment of bipolar I disorder
 - Acute treatment of adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate
 - Maintenance treatment of adults as monotherapy and as adjunct to lithium or valproate
- Adjunctive treatment of adults with major depressive disorder (MDD)

Limitations of Use:

- The ability of ABILIFY MYCITE to improve patient compliance or modify aripiprazole dosage has not been established.
- The use of ABILIFY MYCITE to track drug ingestion in "real-time" or during an emergency is not recommended because detection may be delayed or not occur.

Overview of the ABILIFY MYCITE® System:

The ABILIFY MYCITE® System is composed of the following components:

- Aripiprazole tablet embedded with an IEM sensor (ABILIFY MYCITE®);
- MYCITE ® Patch (wearable sensor) that detects the signal from the IEM sensor after ingestion and transmits data to a smartphone;
- MYCITE APP - a smartphone application (app) which is used with a compatible smartphone to display information for the patient;
- Web-based portal for healthcare professionals and caregivers

Prior to initial patient use of the ABILIFY MYCITE® System, facilitate use of the combination product and its components (patch, app, portal) and ensure the patient is capable and willing to use smartphones and apps. Before using any component of the ABILIFY MYCITE® System, instruct patients to:

- Download the MYCITE APP and follow all the Instructions for Use.

- Ensure that the app is compatible with their specific smartphone.

Although most ingestions will be detected within 30 minutes, it may take up to two hours for the smartphone app and web portal to detect the ingestion of ABILIFY MYCITE®; in some cases, the ingestion of the tablet may not be detected. If the tablet is not detected after ingestion, do not repeat the dose. The status of the MYCITE Patch is indicated by a status icon in the app to inform the user that the patch is properly adhered and fully functioning. Instruct patients to ensure that the app is paired with the patch prior to use.

ABILIFY MYCITE® will require manual review PA on a case-by-case basis using all of the following:

APPROVAL CRITERIA and needed information:

- Prescriber must explain and submit documentation to substantiate the medical necessity of beneficiary receiving the drug-device combination over receiving aripiprazole tablet, another preferred oral antipsychotic agent, or a long-acting injectable antipsychotic;
- Prescriber must submit documentation detailing how the beneficiary will be monitored including:
 - Who will be monitoring compliance
 - Whose smartphone will receive the data especially if the beneficiary does not have one
 - How will beneficiary receive additional MYCITE patches if needs more than 7 per month
 - Provide treatment plan and corrective action plan if noncompliant;
- Approval for a maximum of 3 months at a time

DENIAL CRITERIA:

- Beneficiary does not meet approval criteria;
- Beneficiary does not remain compliant on therapy

CONTINUATION CRITERIA:

- Beneficiary must be compliant on medication

QUANTITY LIMIT:

- Quantity limit of 1 tablet daily; #30 for 30 days

EFFECTIVE IMMEDIATELY (Firdapse® only):

8) FIRDAPSE®/RUZURGI (amifampridine) 10mg tablets

FIRDAPSE® is a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults. Ruzurgi is currently not on the market, but once available it will be indicated for ages 6-17 years old.

Lambert-Eaton myasthenic syndrome (LEMS) is a rare presynaptic disorder of neuromuscular transmission in which quantal release of acetylcholine (ACh) is impaired, causing a unique set of clinical characteristics, which include proximal muscle weakness, depressed tendon reflexes, posttetanic potentiation, and autonomic changes. The initial presentation can be similar to that of myasthenia gravis. Around 60% of those with LEMS have an underlying malignancy, most commonly small-cell lung cancer. If LEMS is caused by an underlying cancer, treatment of the cancer usually leads to resolution of the symptoms.^[3] Treatment usually consists of chemotherapy with radiation therapy in those with limited disease. Other possible treatments include IVIG, Prednisolone, plasma exchange, pyridostigmine, amifampridine and guanidine.

DOSING:

- The recommended starting dosage is 15 mg to 30 mg daily taken orally in divided doses (3 to 4 times daily).

- Starting dosage is 15 mg daily for patients with renal impairment, hepatic impairment, and in known N-acetyltransferase 2 (NAT2) poor metabolizers
- Dosage can be increased by 5 mg daily every 3 to 4 days.
- Dosage is not to exceed a maximum of 80 mg daily.
- The maximum single dose is 20 mg.

▲ DENOTES PULLED FROM CLINICAL TRIAL NCT01377922 OR NCT02970162

APPROVAL CRITERIA and needed information:

- Manual review on a case-by-case basis;
- ≥18 years of age;
- Confirmed diagnosis of LEMS based on either neurophysiology studies or a positive anti-P/Q type voltage-gated calcium channel antibody test;
- Current chart notes;
- If receiving peripherally acting cholinesterase inhibitors, a stable dose is required for at least 7 days ▲;
- If receiving oral immunosuppressants, a stable dose is required for the last 30 days ▲;
- Negative pregnancy test;
- Provide labs including renal and liver function
 - Creatinine clearance from 15-90ml/min must start on lower dose of 15mg per day; no dosage recommendations for ESRD
 - Any decrease in liver function requires a lower starting dose of 15mg per day;
- Provide the Quantitative Myasthenia Gravis (QMG) score for baseline;
- Provide the medical necessity over guanidine hydrochloride, IVIG, and immunosuppressants (such as azathioprine) if not currently taking;
- If diagnosed with cancer, provide treatment plan

DENIAL CRITERIA:

- < 18 years old;
- No confirmation of the LEMS diagnosis;
- History of seizures or taking other medications that can lower the seizure threshold ▲;
- Pregnant;
- End stage renal disease;
- Caution with lactation;
- Use of guanidine hydrochloride in the last 7 days;
- Currently uncontrolled asthma due to increased respiratory infections with this medication ▲

CONTINUATION CRITERIA:

- Current QMG score showing improvement;
- Not pregnant;
- Current labs to monitor kidney and liver function;
- Current chart notes

QUANTITY EDITS:

- #240 / 30 days

EFFECTIVE IMMEDIATELY:

9) BALVERSA™ (erdafitinib) 3mg, 4mg and 5mg tablets

BALVERSA™ is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC), that has

- susceptible FGFR3 or FGFR2 (fibroblast growth factor receptor) genetic alterations AND
- progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

- Patients were selected for the treatment of locally advanced or metastatic urothelial carcinoma with BALVERSA™ based on the presence of susceptible FGFR genetic alterations in tumor specimens as detected by an FDA-approved companion diagnostic. <http://www.fda.gov/CompanionDiagnostics>
- This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

DOSING:

The recommended starting dose of BALVERSA™ is 8 mg (two 4 mg tablets) orally once daily, with a dose increase to 9 mg (three 3 mg tablets) once daily based on serum phosphate (PO₄) levels and tolerability at 14 to 21 days. Assess serum phosphate levels 14 to 21 days after initiating treatment. Increase the dose of BALVERSA™ to 9 mg once daily if serum phosphate level is < 5.5 mg/dL, and there are no ocular disorders or Grade 2 or greater adverse reactions. Monitor phosphate levels monthly for hyperphosphatemia. Dose may be reduced up to four times with lowest dose of 4mg per day.

▲ DENOTES PULLED FROM CLINICAL TRIAL NCT02365597

APPROVAL CRITERIA and information needed:

- Manual review on a case-by-case basis;
- ≥18 years old;
- Metastatic or surgically unresectable urothelial cancer with presence of FGFR alteration documented by FDA-approved companion diagnostic with disease progression on prior chemotherapy;
- Chart notes;
- Provide the following:
 - Current labs including CBC
 - Serum phosphate level
 - Pregnancy tests results if applicable
 - Baseline ophthalmological examination;
- ECOG ≤2
- Currently erdafitinib is considered category 2A in the treatment of urothelial cancer per the NCCN guidelines--Provide the medical necessity of erdafitinib over other agents indicated as category 1 in the NCCN guidelines

DENIAL CRITERIA:

- Doesn't meet the above approval diagnosis;
- Pregnancy;
- Hold if received chemotherapy or definitive radiotherapy within the last 2 weeks ▲;
- Must withhold BALVERSA™ if serum phosphate is ≥7 mg/dL until returns to < 5.5mg/dL or baseline. Has persistent phosphate level greater than upper limit of normal (ULN) during screening (within 14 days of treatment and prior to Cycle 1 Day 1) and despite medical management ▲;
- Grade 4 Central Serous Retinopathy/Retinal Pigment Epithelial Detachment (CSR/RPED) and withhold ;
- Caution use with CYP2C9 or CYP3A4 inhibitors or inducers

CONTINUATION CRITERIA:

- Monthly ophthalmological examination during the first 4 months of treatment and every 3 months afterward;
- Provide current chart notes
- Provide current labs including serum phosphate;
- Discontinue if experiences disease progression or unacceptable toxicity

DOSING ADJUSTMENT / MODIFICATION:

- Withhold BALVERSA™ if serum phosphate level ≥ 7 mg/dL (consider adding phosphate binder until serum phosphate < 5.5 mg/dL)—PI has detailed modification schedule;
- Withhold BALVERSA™ if \geq Grade 1 CSR/RPED—PI has detailed modification schedule based on severity

QUANTITY EDITS:

- 3mg tablet; #84 per 28 days
- 4mg tablet; #56 per 28 days
- 5mg tablet; #28 per 28 days

EFFECTIVE October 1, 2019:

10) ALPHA-1 PROTEINASE INHIBITORS

Alpha-1 Proteinase Inhibitors are indicated for chronic augmentation and maintenance therapy in adults with Alpha-1 Antitrypsin Deficiency (AATD) and clinical evidence of emphysema with the goal to slow down the progression of emphysema.

The GOLD 2019 guidelines state that clinical trials to assess efficacy with spirometric outcome for AAT augmentation therapy for AATD patients has never been done, but observational studies of treated vs non-treated patients shows an effective improvement in patients with predicted FEV1 of 35-49 percent. This limitation is also listed on each of the drugs' package inserts. Also, non-smokers or ex-smokers with an FEV1 of 35-60% are the most suitable for AATD augmentation therapy.

Current available products with dosing:

- 60 mg/kg body weight IV once weekly with varying administration rates
 - Prolastin-C®: 0.08 mL/kg/min by patient response and comfort
 - Aralast NP: 0.02 mL/kg/min by patient response and comfort
 - Glassia: 0.02 mL/kg/min by patient response and comfort
 - Zemaira®: 0.08 mL/kg/min by patient response and comfort

Currently Alpha-1 Proteinase Inhibitors have no prior authorization criteria and would process at point-of-sale without submitting a PA. The DUR Board voted to make this class of medications manual review with the following criteria.

APPROVAL CRITERIA with needed information:

- Age ≥ 18 years old;
- Manual review on a case-by-case basis;
- Request from pulmonologist;
- Required diagnoses consistent with indication
 - Diagnosis of emphysema in the previous 2 years; AND
 - Diagnosis of alpha-1 antitrypsin deficiency in the previous 2 years
- Documentation of smoking status—must be a current non-smoker and need confirmation with carbon monoxide test;
- Documentation of low serum concentration of AAT $\leq 11\mu\text{M/L}$ or $\leq 80\text{mg/dL}$ OR documentation of high-risk homozygous protein phenotypes (i.e. PiZZ, PiSZ, or Pi (null, null));
- Baseline PFTs with FEV1 30-65%;
- Current chart notes with weight for calculating dosage;
- Continued optimal conventional treatment for emphysema (e.g. bronchodilators, supplemental oxygen if needed, etc.)

DENIAL CRITERIA:

- Does not meet above approval criteria;

- Pregnant;
- Request for diagnoses considered investigational (i.e. Cystic Fibrosis, no AATD)
- Billed diagnosis of Immunoglobulin A (IgA) deficiency (IgA < 15mg/dL)
 - D80.2 Selective deficiency of immunoglobulin A (IgA)

CONTINUATION CRITERIA:

- Current chart notes;
- Documentation of elevation of AAT levels above baseline;
- Continued use of conventional treatment for emphysema;
- Current PFTs

QUANTITY EDITS:

- Dose is weight-based; appropriateness of requested dose will be evaluated.

EFFECTIVE IMMEDIATELY:

11) HEPATITIS C VIRUS (HCV) TREATMENT IN PEDIATRICS

Until recently, treatment with Direct-Acting Antivirals (DAA) for pediatric patients was not indicated. Now three DAAs along with Ribavirin are available for our pediatric population with chronic HCV.

PDL effective 4/1/2018

Preferred Drugs that require manual review for prior authorization

- Epclusa® (sofosbuvir/velpatasvir)
- Zepatier® (elbasvir/grazoprevir)
- Mavyret™ tablet (glecaprevir and pibrentasvir)
- Ribavirin capsule 200mg, Ribavirin tablet 200mg

Nonpreferred agents

- Harvoni® (ledipasvir-sofosbuvir) tablet
- Incivek® (telaprevir) tablet
- Infergen® (interferon alfacon-1) vial
- Moderiba® (ribavirin) dosepack
- Olysio® (simeprevir) capsule
- Pegasys® (peginterferon alpha-2a) pen, vial
- PegIntron® (peginterferon alpha-2b) vial kit
- PegIntron® Redipen® (peginterferon alpha-2b) pen kit
- Rebetol® (ribavirin) solution
- Ribapak® (ribavirin) dosepak
- Sovaldi® (sofosbuvir) tablet
- Technivie® (ombitasvir and ritonavir)
- Victrelis® (beceprevir) capsule
- Viekira Pak™ (ombitasvir-paritaprevir-ritonavir & dasabuvir) tablet dosepak
- Vosevi® (sofosbuvir, velpatasvir, and voxilaprevir tablet, film coated) tablet
- Daklinza® (daclatasvir tablet)

For infants born infected with HCV due to mother-to-child transmission, around 25-50% are spontaneously cured of HCV by age 3. While there is debate about the value of HCV-RNA when infants are in their first year of life, it is not recommended due to the cost of testing and lack of intervention or treatment before age 3.

The only drug indicated for treatment for those aged 3 years or more is ribavirin when used in combination with interferon alfa-2b for treatment of chronic hepatitis C with compensated liver disease. For adolescents aged at least 12 years or weighing 35 kg or greater (for Sovaldi and Harvoni) and 45 kg (for Mavyret) without cirrhosis or with compensated cirrhosis.

SUMMARY OF AVAILABLE HEPATITIS C TREATMENTS

HCV Drug	Age	Indication
Ribavirin	3+	In combination with interferon alfa-2b are indicated for the treatment of Chronic Hepatitis C (CHC) in patients 3 years of age and older with compensated liver disease
Olysio (simeprevir)	18+	No longer available
Sovaldi (sofosbuvir)	12+	Indicated for the treatment of chronic HCV genotype 2 or 3 infection in pediatric patients 12 years of age and older or weighing at least 35 kg without cirrhosis or with compensated cirrhosis for use in combination with ribavirin
Harvoni (ledipasvir/sofosbuvir)	12+	Indicated for the treatment of pediatric patients 12 years of age and older or weighing at least 35 kg with HCV genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
Viekira Pak (ombitasvir/parutaprevir/ritonavir; dasabuvir)	18+	Indicated for adults with genotype 1b without cirrhosis or with compensated cirrhosis; genotype 1a without cirrhosis or with compensated cirrhosis and use with ribavirin
Viekira XR	18+	Indicated for adults with genotype 1b without cirrhosis or with compensated cirrhosis; genotype 1a without cirrhosis or with compensated cirrhosis and use with ribavirin
Technivie (ombitasvir/paritaprevir/ritonavir)	18+	Indicated for genotype 4 without cirrhosis or with compensated cirrhosis along with ribavirin
Daklinza (daclatasvir)	18+	Indicated for genotype 1 or genotype 3 with sofosbuvir +/- ribavirin
Zepatier (elbasvir/grazoprevir)	18+	Indicated for genotype 1 or genotype 4
Epclusa (sofosbuvir/velpatasvir)	18+	Indicated for genotype 1,2,3,4,5,and 6 without cirrhosis or with compensated cirrhosis and with decompensated cirrhosis with ribavirin
Mavyret (glecaprevir/pibrentasvir)	12+	Indicated for the treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis Indicated for the treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both
Vosevi (sofosbuvir/velpastavir/voxilaprevir)	18+	Indicated for patients without cirrhosis or with compensated cirrhosis genotype 1,2,3,4,5 and 6 without previously treated with a NS5A inhibitor AND genotype 1a or 3 previously treated with sofosbuvir without a NS5A inhibitor

APPROVAL CRITERIA with information needed:

- Manual review on a case-by-case basis;
- Ribavirin will be considered for patients ≥ 3 years old;
- Sovaldi, Harvoni and Mavyret
 - Sovaldi—must be ≥ 12 years old or ≥ 35 kg
 - Harvoni—must be ≥ 12 years old or ≥ 35 kg
 - Mavyret—must be ≥ 12 years old or ≥ 45 kg
- Until age indications change for the remaining Direct-Acting Antivirals (DAAs), these medications will be considered for patients ≥ 18 years old;
- Preferred Drug List (PDL) will remain the same with Zepatier, Epclusa and Mavyret remaining preferred at this time;
- Provide a completed Hepatitis C Virus (HCV) request form and provide all documentation requested on the form;
- Provide current chart notes;
- Provide current labs including CBCs, LFTs, urine drug screens when applicable, documentation of genotype, HIV test results, and documentation of Child-Pugh score;
- Documentation of Metavir score—liver biopsy sampling in children may be problematic. Liver elastography (i.e. FibroSCAN®) and patented serum panels (i.e. FibroStat®) are less invasive and probably more appropriate in children;
- Clinical review will require the documentation of medical necessity for HCV pediatric patients

DENIAL CRITERIA:

- Medical necessity is not established

EFFECTIVE IMMEDIATELY:

12) TIBSOVO® (ivosidenib) 250mg tablet

TIBSOVO® is an isocitrate dehydrogenase-1 (IDH1) inhibitor indicated for the treatment of acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test in:

- Adult patients with newly-diagnosed AML who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.
- Adult patients with relapsed or refractory AML.

Patients are selected for the treatment of AML with TIBSOVO® based on the presence of IDH1 mutations in the blood or bone marrow. Patients without IDH1 mutations at diagnosis should be retested at relapse because a mutation in IDH1 may emerge during treatment and at relapse. Information on FDA-approved tests for the detection of IDH1 mutations in AML is available at <http://www.fda.gov/CompanionDiagnostics>.

DOSING:

The recommended dose of TIBSOVO® is 500 mg taken orally once daily until disease progression or unacceptable toxicity. For patients without disease progression or unacceptable toxicity, treat for a minimum of 6 months to allow time for clinical response.

▲ DENOTES PULLED FROM CLINICAL TRIAL NCT02074839

APPROVAL CRITERIA with information needed:

- Manual review on a case-by-case basis;
- ≥ 18 years old for relapsed or refractory AML and ≥ 75 years old for newly-diagnosed AML with comorbidities that preclude intensive induction chemotherapy;
- Provide documentation of the presence IDH1 mutations of the R132 gene ▲;

- ECOG \leq 2;
- Provide current chart notes with documentation of previous therapy;
- Provide the following labs ▲
 - CBC with platelets \geq 20,000/ μ L (check weekly for first month, every other week for 2nd month then monthly for treatment duration)
 - Liver function panel (safety in Child-Pugh C is unknown)
 - SCr/BUN (safety in severe renal impairment eGFR $<$ 30 mL/min/1.73m² is unknown)
 - Creatine phosphokinase (weekly for first month of therapy);
- Documentation of pregnancy status if applicable;
- Baseline electrocardiogram (ECG) (repeat weekly for first 3 weeks of therapy then at least monthly for treatment duration)

DENIAL CRITERIA:

- Disease progression or unacceptable toxicity;
- QTc interval prolongation with signs/symptoms of life-threatening arrhythmia;
- Guillain-Barre' syndrome diagnosis;
- Multiple cardiac issues were excluded from the clinical trial ▲
 - NYHA class III or IV CHF or LVEF $<$ 40% by ECHO or MUGA scan
 - Myocardial infarction in the last 6 months
 - Uncontrolled angina or uncontrolled ventricular arrhythmias
 - Heart-rate corrected QT (QTc) interval \geq 450ms with other factors that can prolong QT interval such as medications;
- Systemic anticancer therapy or radiation $<$ 14 days prior to initiation ▲;
- Concomitant use with drugs that prolong QTc (e.g. anti-arrhythmic meds, fluoroquinolones, triazole anti-fungals or 5-HT₃ receptor antagonists) and CYP3A4 inhibitors

DOSE MODIFICATION:

- Differentiation syndrome—interrupt if severe symptoms, resume if Grade \leq 2;
- Noninfectious leukocytosis—interrupt if leukocytosis not improved with hydroxyurea;
- QTc 480-500 msec—Interrupt; restart when QTc \leq 480 msec;
- QTc \geq 500 msec—Interrupt; resume at reduced dose when QTc \leq 480 msec;
- Grade 3 or higher toxicity—Interrupt until resolve to Grade 2 or lower; resume with lower dose;
- Use with strong CYP3A4 inhibitor—reduce dose to 250mg daily

CONTINUATION CRITERIA:

- No disease progression or unacceptable toxicity;
- Treat minimum of 6 months if tolerated to allow time for clinical response;
- Provide updated labs, ECG and chart notes

QUANTITY EDITS:

- #60/ 30 days

EFFECTIVE IMMEDIATELY (VYNDAQEL® only):

13) VYNDAQEL® (tafamidis meglumine) 20mg capsule AND VYNDAMAX™ (tafamidis) 61mg capsule

Vyndamax™ should be on the market in the near future.

VYNDAQEL® and VYNDAMAX™ are transthyretin stabilizers indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. The cardiac form of transthyretin amyloidosis affects the heart. People with cardiac amyloidosis may have an abnormal heartbeat (arrhythmia), an enlarged heart (cardiomegaly), or orthostatic hypertension. These abnormalities can lead to progressive heart failure and death.

DOSING:

- VYNDAQEL® 80 mg orally once daily OR
- VYNDAMAX™ 61 mg orally once daily
- VYNDAMAX™ and VYNDAQEL® are not substitutable on a per mg basis.

Transthyretin amyloidosis is a slowly progressive condition characterized by the buildup of abnormal deposits of a protein called amyloid (amyloidosis) in the body's organs and tissues.

▲ DENOTES PULLED FROM CLINICAL TRIAL NCT01994889

APPROVAL CRITERIA with information needed:

- Manual review on a case-by-case basis;
- ≥18 years old;
- Negative pregnancy test if applicable;
- Medical history of Heart Failure (HF) with at least 1 prior hospitalization for HF or clinical evidence of HF (without hospitalization) manifested by signs or symptoms of volume overload or elevated intracardiac pressures ▲;
- Baseline NYHA class;
- Documentation of variant TTR genotype and/or TTR precursor protein identification by immunohistochemistry, scintigraphy and mass spectrometry ▲;
- Baseline 6-Minute Walk Test ▲;
- Baseline Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS) score.

▲

DENIAL CRITERIA:

- NYHA class IV ▲;
- Does not meet the approval criteria;
- Prior liver or heart transplant or has implanted cardiac mechanical assist device ▲;
- Pregnant

CONTINUATION CRITERIA:

- Provide current chart notes;
- Recipient's pharmacy profile will be reviewed for medication adherence;
- Provide documentation of any hospitalizations since previous approval;
- Repeat 6-Minute Walk Test every 6 months
- Repeat KCCQ-OS score every 6 months; don't expect to see positive results until at least month 18

QUANTITY EDITS:

- VYNDAQEL® 20mg--#120/30 days
- VYNDAMAX™ 61mg (when available)--#30/30 days

EFFECTIVE IMMEDIATELY:

14) ERLOTINIB (TARCEVA®) 25mg, 100mg and 150mg tablets

Tarceva® was FDA approved in 2004, and the Arkansas Medicaid program did not place manual review criteria at that time. Recently Tarceva® became available by multiple manufacturers. Given the specific diagnoses, adverse effects and monitoring, the DUR Board voted to make erlotinib manual review.

TARCEVA® is a kinase inhibitor indicated for:

- The treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance,

or second or greater line treatment after progression following at least one prior chemotherapy regimen.

- First-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine.
- Safety and efficacy of TARCEVA® have not been established in patients with NSCLC whose tumors have other EGFR mutations.
- TARCEVA® is not recommended for use in combination with platinum-based chemotherapy. (cisplatin or carboplatin with gemcitabine or docetaxel).

DOSING:

The recommended daily dose of TARCEVA® for **NSCLC** is 150 mg taken on an empty stomach, i.e., at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity occurs.

The recommended daily dose of TARCEVA® for **pancreatic cancer** is 100 mg taken once daily in combination with gemcitabine. Take TARCEVA® on an empty stomach, i.e., at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity occurs

▲ DENOTES PULLED FROM CLINICAL TRIALS NCT02774278 OR NCT01664533 FOR NSCLC PATIENTS

▲▲ DENOTES PULLED FROM CLINICAL TRIALS NCT02694536 OR NCT00810719 FOR PANCREATIC PATIENTS

APPROVAL CRITERIA with information needed:

- Manual review on a case-by-case basis;
- ≥18 years old;
- Must have a diagnosis consistent with the FDA approved indications listed above;
- For NSCLC patient—documentation on the presence of EGFR exon 19 deletions or exon 21 substitution mutations using an FDA-approved test
- Pregnancy test results if applicable;
- ECOG ≤ 2;
- Documentation of smoking status;
- Provide the following labs:
 - CBC
 - Renal function and serum electrolytes
 - Liver function tests
 - INR if taking warfarin
 - Clinical trial required ▲▲
 - leukocytes ≥ 3,000/μL
 - absolute neutrophil count ≥ 1,500/ μL
 - platelets ≥ 100,000/ μL
 - total bilirubin ≤ 1.5 X institutional upper limit of normal
 - AST(SGOT)/ALT(SGPT) ≤ 3 X institutional upper limit of normal, unless the liver is involved with tumor, in which case the AST/ALT must be ≤ 5 X institutional upper limit of normal
 - creatinine clearance ≥ 50 mL/min/1.73 m², as measured by 24hour collection OR
 - creatinine ≤ 1.5 X institutional upper limit of normal;
- For NSCLC patient—documentation of disease progression following course of standard chemotherapy or participants unwilling/unable to undergo chemo ▲;

- For pancreatic cancer patient—documentation of combination of gemcitabine with TARCEVA®
- For pancreatic cancer patient--prior adjuvant chemotherapy is allowed provided that patients did not receive gemcitabine and the chemotherapy was completed > six months prior to initiation of therapy. ▲ ▲

DENIAL CRITERIA:

- NSCLC patient has EGFR mutations different than the approved indication;
- Denied if NSCLC patient continues to take a platinum-based chemotherapy;
- Pregnancy;
- Discontinue or deny if have any of the following:
 - Gastrointestinal perforations
 - Bullous and exfoliative skin disorders
 - Ocular disorders such as corneal perforation, ulceration or severe keratitis
 - Diagnosis of Interstitial Lung Disease (ILD);
- Denied if pancreatic cancer patient is not taking gemcitabine;
- Denied if patient has brain metastases ▲ & ▲ ▲;
- Denied if pancreatic cancer patient had prior systemic treatment for metastatic disease ▲ ▲

DOSE MODIFICATIONS:

- Use of CYP3A4 inhibitors—reduce TARCEVA® by 50mg decrements
- Use of CYP3A4 inducers—increase TARCEVA® by 50mg increments to max of 450mg
- Concurrent smoking—increase TARCEVA® by 50mg increments to max of 300mg
- Use of Proton Pump inhibitors—avoid concomitantly
- Reduce TARCEVA® by 50mg decrements when restarting therapy after toxicity is resolved
 - Withhold for severe renal impairment (risk for Hepatorenal syndrome or renal failure)
 - Withhold for hepatotoxicity (risk for Hepatorenal syndrome or hepatic failure)
 - No pre-existing hepatic impairment with bilirubin >3X ULN or transaminases are >5X ULN
 - Pre-existing hepatic impairment with doubling of bilirubin or tripling transaminases over baseline
 - Discontinue if above not resolved or significantly improved within 3 weeks

CONTINUATION CRITERIA:

- No disease progression or unacceptable toxicity;
- Current labs listed above and chart notes

QUANTITY EDITS:

- 25mg tablets #60/ 30 days
- 100mg tablets #30/ 30 days
- 150mg tablets #30/ 30 days

FRIENDLY REMINDERS:

1. **Effective March 1, 2019**, Arkansas Medicaid implemented **PASSE (Provider-Led Arkansas Shared Savings Entity)**, a new Medicaid program to address the needs of individuals who have intensive behavioral health and intellectual and developmental disabilities service needs. The PASSE organizations administer all medical needs and all pharmacy prescription drug needs for all PASSE members. **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: <https://humanservices.arkansas.gov/about-dhs/dms/passe>. For questions about each PASSE organization, please refer to this website for contact information: <https://humanservices.arkansas.gov/about-dhs/dms/passe/contact-us>
2. **MAT (Medication Assisted Treatment) with Buprenorphine/naloxone and psychosocial treatment or counseling:** Per the TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: Treatment Improvement Protocol (TIP) Series 40*: **“Pharmacotherapy alone is rarely sufficient treatment for drug addiction. For most patients, drug abuse counseling—individual or group—and participation in self-help programs are necessary components of comprehensive addiction care.** As part of training in the treatment of opioid addiction, physicians should at a minimum obtain some knowledge about the basic principles of brief intervention in case of relapse. **Physicians considering providing opioid addiction**

care should ensure that they are capable of providing psychosocial services, either in their own practices or through referrals to reputable behavioral health practitioners in their communities. In fact, DATA 2000 stipulates that when physicians submit notification to SAMHSA to obtain the required waiver to practice opioid addiction treatment outside the OTP setting, they must attest to their capacity to refer such patients for appropriate counseling and other nonpharmacological therapies.”

<http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf>

Per ASAM National Practice Guideline, in Part 5: Buprenorphine, Summary of Recommendations, # (5) “Psychosocial treatment should be implemented in conjunction with the use of buprenorphine in the treatment of opioid use disorder.” <https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>

- 3. Chronic Pain Patients Who Do Not Need Treatment for Addiction:** Per the TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: Treatment Improvement Protocol (TIP) Series 40*: “Patients who need treatment for pain *but not for addiction* should be treated within the context of their regular medical or surgical setting. They should *not* be transferred to an opioid maintenance treatment program simply because they are being prescribed opioids and have become physically dependent on the opioids during their medical treatment.” Substance Abuse and Mental Health Services Administration ([SAMHSA](http://www.samhsa.gov)) Center for Substance Abuse Treatment. <http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf>

- 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 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. Suboxone Film (buprenorphine/naloxone) once daily dosing:** as stated in the Suboxone Film package insert, the FDA approved dose for treating opioid addiction is **prescribing the total daily dose as one single daily dose.** “After treatment induction and stabilization, the maintenance dose of SUBOXONE sublingual film is generally in the range of 4 mg/1 mg buprenorphine/naloxone to 24 mg/6 mg buprenorphine/naloxone per day depending on the individual patient and clinical response. The recommended target dosage of SUBOXONE sublingual film during maintenance is 16 mg/4 mg buprenorphine/naloxone/day **as a single daily dose.** Dosages higher than 24 mg/6 mg daily have not been demonstrated to provide a clinical advantage.”

Per ASAM National Practice Guidelines, the bold and italics were added for emphasis, but the following statement is pulled from the “At Induction” section of “Part 5: Buprenorphine”, under Dosing, “Once it has been established that the initial dose is well tolerated, the buprenorphine dose can be increased fairly rapidly to a **dose that provides stable effects for 24 hours and is clinically effective**”.

<https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>

- 6. CIRCUMVENTING MEDICAID LIMITS FOR OPIOIDS AND BENZODIAZEPINES:**

Beneficiaries who pay *cash* for opioids to avoid Medicaid dose and quantity limits *or pay cash in addition to* the opioids paid for by Medicaid, result in a much higher daily MME than what is calculated in the Medicaid system edits, are above the CDC recommendations, and could *put the patient at risk for overdose*. **According to the CDC, the number of Arkansas deaths due to drug overdose increased 10.2% from December 2016 to December 2017.**

- 7. REGARDING MANUAL REVIEW PA REQUESTS:** Prior authorization (PA) requests for drugs that require a clinical manual review prior approval, require a prior authorization request for a drug as an *exception* to established point of sale prior approval criteria algorithm, or require a request for non-preferred drugs on the PDL, are all reviewed on a *case-by-case basis* through a manual review process. All manual review requests for prior authorization *require, at a minimum, the prescriber to provide a letter explaining the medical necessity* for the requested drug *along with all written documentation to substantiate* the medical necessity, e.g., chart notes, pharmacy printouts for cash, printout of private insurance paid drugs, lab results, etc. **Please note that starting the requested drug, including long-acting injectable antipsychotic agents, 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 not necessitate Medicaid Pharmacy Program approval of the requested drug.

8. **“CLAIM EDITS”** referred to in this memo include quantity edits, cumulative quantity edits, monthly quantity edits, age edits, gender edits, accumulation quantity edits, and daily dose edits.
9. **CHANGE IN MANUAL REVIEW PA FOR THE AGE OF CHILDREN PRESCRIBED ANTIPSYCHOTIC AGENTS, EFFECTIVE JANUARY 1, 2017:** 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 board certified child & adolescent psychiatrist.
10. **SECOND GENERATION ANTIDEPRESSANTS, TRAZODONE, AND TRICYCLIC ANTIDEPRESSANTS PRESCRIBED TO CHILDREN ≤ 3 YEARS OF AGE, EFFECTIVE MARCH 8, 2017:** 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.
11. **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 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. 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/>.
12. **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 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.
13. **REFILL TOO SOON ACCUMULATION LOGIC for NON-CONTROLLED DRUGS:** 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* 12 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.

Effective August 8, 2018, the RTS logic with Early Refill Accumulation Limited edit was revised for the **non-controlled drugs** which now **allow an accumulation of 12 days' supply during the previous 180-day period**.

Effective February 14, 2018, the RTS logic with Early Refill Accumulation Limit edit is **revised for the controlled drugs**. The revised edit for **controlled drugs** will only allow an extra 7-days' supply accumulation through early fills in previous 180-day period rather than an accumulation of an extra 15-days' supply. The RTS logic with Early Refill Accumulation Limit edit for non-controlled drugs will remain as is. 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.

14. **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.
15. **ANTIPSYCHOTIC AGENT CRITERIA FOR CHILDREN < 18 YEARS OF AGE have an ongoing requirement for labs** for metabolic monitoring every 6 months. When any provider sends a patient, who is less than 18 years of age for the required metabolic labs 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.
16. **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.
17. **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.
18. **FOR NON-PDL DRUGS AND FOR NON-ANTIPSYCHOTIC 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.
19. **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.
20. **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

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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

- 21. 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.