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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: November 13, 2023
 SUBJ: **AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR/DRC Board October 18, 2023 meeting for the following:**
Manual review criteria for: Skyclarys™ (omaveloxolone), Vanflyta® (quizartinib), and Akeega™ (niraparib/abiraterone)

Preferred Drug List (PDL) therapeutic classes without PA criteria: Colony stimulating factors

Preferred Drug List (PDL) therapeutic classes with PA criteria: Movement disorder agents (Austedo®, Austedo XR®, Ingrezza®, tetrabenazine), long-acting opioids, lipotropics (bile acid sequestrants, fibric acid agents, PCSK9 inhibitors, ezetimibe, Nexletol®/Nexlizet®, Juxtapid®, Omega-3 fatty acids)

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 1) SKYCLARYS™ (omaveloxolone) 50 mg capsule.....12

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I. ANNOUNCEMENTS

1) RESPIRATORY SYNCTIAL VIRUS

ARKANSAS MEDICAID RSV PROPHYLAXIS COVERAGE POLICY

Arkansas Medicaid will follow ACIP/CDC recommendations for RSV prophylaxis.

- **SYNAGIS (palivizumab)**
 - SYNAGIS will continue to require prior authorization (PA). Fax the PA request to 800-424-7976.
 - Documentation needed for PA review:
 - Medical necessity of SYNAGIS over BEYFORTUS
 - Discharge summary and current chart notes as usual
 - Completed form [Arkansas Medicaid Synagis Prior Authorization Request Form \(Year 2023-24\) \(magellanrx.com\)](https://magellanrx.com)
 - Requests for SYNAGIS will continue to use AAP guidelines from 2014 in addition to medical necessity over BEYFORTUS.
 - If SYNAGIS is approved, PA renewals will require prescriber attestation that WebIZ has been checked prior to PA submission, and documentation that the patient has not gotten BEYFORTUS since the last SYNAGIS dose.
 - If < 5 SYNAGIS doses have been given, the patient can be changed to BEYFORTUS.
- **BEYFORTUS (nirsevimab)**
 - BEYFORTUS is available through the Vaccines for Children (VFC) program, and no prior authorization is required.
 - ACIP recommends 1 dose of nirsevimab for all infants aged <8 months born during or entering their first RSV season (50 mg for infants weighing <5 kg [<11 lb.] and 100 mg for infants weighing ≥5 kg [≥11 lb.]). Providers should bill with procedure code 90380 or 90381 for the administration and 96380 or 96381 for documentation of counseling.
 - ACIP recommends 1 dose of nirsevimab (200 mg, administered as two 100 mg injections given at the same time at different injection sites) for infants and children aged 8–19 months who are at increased risk for severe RSV disease and entering their second RSV season. Providers should bill with procedure code 90380 U1 or 90381 U1 for the administration and 96380 or 96381 for documentation of counseling.
 - The recommendations for nirsevimab apply to infants and children recommended to receive palivizumab by AAP.
 - If BEYFORTUS has been given, the patient cannot be given SYNAGIS.
- **RSVpreF (maternal vaccine)**
 - RSVpreF is available through the Vaccines for Children (VFC) program for pregnant women less than 19 years of age.
 - RSVpreF will be covered as a normal adult vaccine and not require a prior authorization for pregnant women 19 years of age and older.
 - ACIP/CDC recommended this product for pregnant women who are 32-36 weeks into pregnancy.
 - Providers should bill procedure codes 90678 or 90679.
- **ABRYSVO (RSV vaccine)**
 - ABRYSVO will be covered as a normal adult vaccine and not require a prior authorization.
 - ACIP/CDC recommended this product be available for adults 60 years of age and older given in one single dose and using shared clinical decision-making.
 - Providers should bill procedure codes 90678 or 90679.
- **AREXVY (RSV vaccine)**
 - AREXVY will be covered as a normal adult vaccine and not require a prior authorization.
 - ACIP/CDC recommended this product be available for adults 60 years of age and older given in one single dose and using shared clinical decision-making.
 - Providers should bill procedure codes 90678 or 90679.

II. PREFERRED DRUG LIST

PDL UPDATE EFFECTIVE JANUARY 1, 2024

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

Non-preferred agents require a prior authorization submission. Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800- 424-7976. Any PA request for an off-label use will be reviewed on a case-by-case basis.

1) COLONY STIMULATING FACTORS

PREFERRED AGENTS

- **FYLNETRA (pegfilgrastim-pbbk) syringe**
- NEUPOGEN (filgrastim) syringe and vial

NON-PREFERRED AGENTS

- FULPHILA (pegfilgrastim-jmbd) syringe
- GRANIX (tbo-filgrastim) syringe and vial
- LEUKINE (sargramostim) vial
- NEULASTA (pegfilgrastim) syringe
- NEULASTA ONPRO® KIT (pegfilgrastim)
- **NYVEPRIA (pegfilgrastim-apgf) syringe**
- NIVESTYM (filgrastim-aafi) syringe and vial
- RELEUKO (filgrastim-ayow) syringe and vial
- ROLVEDON (eflapegrastim-xnst) syringe
- STIMUFEND (pegfilgrastim-fpgk) syringe
- UDENYCA (pegfilgrastim -cbqv) syringe and autoinjector
- ZARXIO (filgrastim-sndz) syringe
- ZIEXTENZO (pegfilgrastim-bmez) syringe

2) VESICULAR MONOAMINE TRANSPORTER 2 (VMAT2) INHIBITORS (new PDL class)

PREFERRED AGENTS with criteria

- **AUSTEDO tablet (deutetrabenazine)**
- **AUSTEDO XR tablet (deutetrabenazine)**
- **INGREZZA capsule (valbenazine)**
- **TETRABENAZINE tablet (generic for Xenazine®)**

NON-PREFERRED AGENTS

- **XENAZINE tablet (tetrabenazine)**

APPROVAL CRITERIA:

Tetrabenazine tablet (POS edits)

- Requires a billed diagnosis of Huntington's Disease with Chorea in the past 3 years
- Quantity edits apply

Austedo®/Austedo XR® tablet (deutetrabenazine)—requires a PA

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have one of the following diagnoses:

- Chorea associated with Huntington's disease
- Moderate to severe tardive dyskinesia (must also meet **ALL** the following DSM-5 criteria)
 - Involuntary athetoid or choreiform movements
 - History of treatment with dopamine receptor blocking agent (DRBA) (e.g., antipsychotics or metoclopramide)
 - Symptoms duration lasting longer than 4 to 8 weeks
- Must be prescribed by or in consultation with a neurologist, psychiatrist, or gastroenterologist (chorea due to metoclopramide)
- Beneficiary should not be approved or continue on this therapy with any of the following:
 - Congenital long QT syndrome or cardiac arrhythmias associated with a prolonged QT interval
 - Hepatic impairment
 - Requires monoamine oxidase inhibitors (MAOIs), any other VMAT2 inhibitor, or reserpine
 - Requires strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion)
 - Poor CYP2D6 metabolizer requires a dose reduction to 36 mg daily
 - Pregnant or breastfeeding
 - Dose requested is > 48 mg/day
 - Develops Neuroleptic Malignant Syndrome
 - Chorea associated with Huntington's disease beneficiary that is suicidal or has untreated or inadequately treated depression
- Prescriber must submit **ALL** the following:
 - Current chart notes with documentation on the impact of TD or chorea symptoms with activities of daily living
 - Completed Medicaid Ingrezza®/Austedo® Statement of Medical Necessity form with the initial request:
<https://ar.magellanrx.com/documents/268611/269351/Ingrezza%20or%20Austedo%20Statement%20of%20Medical%20Necessity/08a1ca71-1cab-9051-d32e-e7929cbaff43>
 - Baseline Abnormal Involuntary Movement Scale (AIMS) form for tardive dyskinesia
 - Data documenting the response to bextropine or other agent of EPS symptoms if applicable
 - Tapering plan with each PA request until beneficiary reaches a stable, maintenance dose
- The initial Austedo® PA will be approved for two (2) months to allow time for titration. Austedo® 6 mg can be approved up to a maximum of #240 tablets (8 tablets per day) during the initial two (2) months of treatment for titration. If additional titration time is needed beyond the original two (2) months, another PA with quantity override would be required. Once compliant on a maintenance dose, PAs may be approved for a maximum of 6 months.

RENEWAL REQUIREMENTS:

- Prescriber must submit the following:
 - Current chart notes
 - Current AIMS score
- Beneficiary must have an improvement from baseline AIMS score or has a positive clinical response

Ingrezza® capsule (valbenazine)—requires a PA

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have one of the following diagnoses:
 - Chorea associated with Huntington's disease
 - Moderate to severe tardive dyskinesia (must also meet **ALL** the following DSM-5 criteria)
 - Involuntary athetoid or choreiform movements
 - History of treatment with dopamine receptor blocking agent (DRBA) (e.g., antipsychotics or metoclopramide)
 - Symptoms duration lasting longer than 4 to 8 weeks
- Must be prescribed by or in consultation with a neurologist, psychiatrist, or gastroenterologist (chorea due to metoclopramide)

- Beneficiary should not be approved or continue on this therapy with any of the following:
 - Has violent behavior or is suicidal
 - Pregnant or breastfeeding
 - Requires monoamine oxidase inhibitors (MAOIs), any other VMAT2 inhibitor, or concomitant strong CYP3A4 inducers (e.g., rifampin, carbamazepine, and phenytoin)
 - Dose requested is > 80 mg/ day
 - Dose requested is > 40 mg/ day when requires strong SYP3A4 inhibitors (e.g., itraconazole, ketoconazole, and clarithromycin) OR has moderate to severe hepatic impairment (Child Pugh score 7-15)
 - Congenital long QT syndrome or cardiac arrhythmias associated with a prolonged QT interval
 - Severe renal impairment (creatinine clearance <30 ml/min)
- Prescriber must submit ALL the following:
 - Current chart notes with documentation on the impact of TD or chorea symptoms with activities of daily living
 - Completed Medicaid Ingrezza®/Austedo® Statement of Medical Necessity form with the initial request:
<https://ar.magellanrx.com/documents/268611/269351/Ingrezza%20or%20Austedo%20Statement%20of%20Medical%20Necessity/08a1ca71-1cab-9051-d32e-e7929cbaff43>
 - Baseline Abnormal Involuntary Movement Scale (AIMS) form for tardive dyskinesia
 - Data documenting the response to benztropine or other agent of EPS symptoms if applicable
- Initial Ingrezza® PA should not exceed 3 months. Once compliant on maintenance dose, PAs may be approved for a maximum of 6 months.

RENEWAL REQUIREMENTS:

- Prescriber must submit the following:
 - Current chart notes
 - Current AIMS score for patients with tardive dyskinesia
- Beneficiary must have an improvement from baseline AIMS score or has a positive clinical response

3) LONG-ACTING OPIOIDS

PREFERRED AGENTS with criteria

- BUTRANS patch (buprenorphine)—**BRAND ONLY preferred**
- MORPHINE SULFATE long-acting tablet (generic for MS Contin®)
- TRAMADOL ER tablet (generic for Ultram ER®)
- **XTAMPZA ER capsule (oxycodone ER)**

NON-PREFERRED AGENTS with criteria

- BELBUCA films (buprenorphine)
- BUPRENORPHINE patch (generic for Butrans®)
- CONZIP capsule (tramadol ER)
- FENTANYL patch (generic for Duragesic®)
- HYDROCODONE ER capsule (generic for Zohydro ER®)
- HYDROCODONE ER tablet (generic for Hysingla ER®)
- HYDROMORPHONE HCl extended-release tablet (generic for Exalgo ER®)
- HYSINGLA ER tablet (hydrocodone ER)
- METHADONE tablet (generic for Dolophine®)
- METHADONE solution
- METHADONE Intensol conc
- MORPHINE SULFATE ER capsule (generic for Avinza®, Kadian®)
- MS CONTIN tablet (morphine sulfate)
- NUCYNTA ER tablet (tapentadol HCl)

- OXYCODONE ER tablet (generic for Oxycontin®)
- OXYCONTIN tablet (oxycodone)
- OXYMORPHONE HCl ER tablet (generic for Opana ER®)
- TRAMADOL ER capsule (generic for Conzip®)
- TRAMADOL ER tablet (generic for Ryzolt®)

APPROVAL CRITERIA:**LONG-ACTING OPIOID CRITERIA FOR PREFERRED AGENTS:**

- Provider must submit the medical necessity of using a long-acting opiate for chronic, non-cancer pain over short-acting opioids or other medications used for pain
- Continuation criteria—Claim for long-acting opiate within the previous 60 days

LONG-ACTING OPIOID CRITERIA FOR NON-PREFERRED AGENTS:

- Fentanyl patch
 - NPO
 - Currently in LTC
 - Cancer diagnosis in the past 12 months
 - No therapeutic duplication with other long-acting opioids
- Morphine sulfate long-acting capsules OR oxycodone long-acting tablet
 - Currently in LTC
 - Cancer diagnosis in the past 12 months
 - No therapeutic duplication with other long-acting opioids
- Methadone HCl (Dolophine®)
 - Cancer diagnosis in the past 12 months
 - No therapeutic duplication with other long-acting opioids
- Methadone oral solution for Neonatal Abstinence Syndrome
 - Infant's age is ≤ 90 days of age at the time drug claim is submitted
 - Quantity of methadone oral solution dispensed is not more than 10 mL for a 30-day supply
 - Incoming claim and the claim in history will not make the total quantity of methadone oral solution more than 10 mL for the previous 30-day supply

OVERDOSE DENIAL CRITERIA:

- An incoming claim for any opioid pain medication will trigger a search of the beneficiary's Medicaid medical diagnoses history for diagnosis of poisoning or overdose in the previous 12 months.
- If a diagnosis for poisoning (overdose) for opioids, narcotics, barbiturates, benzodiazepines, or "unspecified drug or substance" is found in the Medicaid medical history in the previous 12 months, an incoming claim for an opioid or benzodiazepine will deny at point of sale.
- Exception
 - Beneficiaries with a cancer diagnosis in the past 12 months will be except from the diagnosis check for poisoning (overdose).

GENERAL DENIAL CRITERIA:

- Medicaid paid claim history contains Suboxone or Subutex in the last 90 days
- Therapeutic duplication with other long-acting opioids
- Provider has not submitted the medical necessity for long-acting opioids
- Opioid claims exceed the current MME limits.

4) LIPOTROPICS (excluding statins)

PREFERRED AGENTS no criteria

- **Bile Acid Sequestrants**
 - CHOLESTYRAMINE light powder for oral suspension (generic for Questran® light, Prevalite®)
 - CHOLESTYRAMINE powder for oral suspension (generic for Questran®)
 - COLESTIPOL granules (generic for Colestid®)
 - COLESTIPOL packet (generic for Colestid®)
 - COLESTIPOL tablet (generic for Colestid®)
- **Cholesterol Absorption Inhibitor**
 - EZETIMIBE tablet (generic for Zetia®)
- **Fibric Acids**
 - FENOFIBRATE tablet 48 mg, 145 mg (generic for Tricor®)
 - FENOFIBRATE tablet 54 mg, 160 mg (generic for Lofibra®)
 - GEMFIBROZIL tablet 600 mg (generic for Lopid®)
- **Niacin**
 - NIACIN ER tablet (generic for Niaspan ER®)

NON-PREFERRED AGENTS

- **Bile Acid Sequestrants**
 - COLESEVELAM powder pack (generic for Welchol®)
 - COLESEVELAM tablet (generic for Welchol®)
 - COLESTID tablet (colestipol)
 - COLESTID packet (colestipol)
 - PREVALITE powder (cholestyramine)
 - QUESTRAN powder (cholestyramine)
 - QUESTRAN LIGHT powder (cholestyramine)
 - WELCHOL powder pack (colesevelam)
 - WELCHOL tablet (colesevelam)
- **Cholesterol Absorption Inhibitor**
 - ZETIA tablet (ezetimibe)
- **Fibric Acids**
 - FENOFIBRATE capsule 134 mg, 200 mg (generic for Lofibra®)
 - FENOFIBRATE capsule 43 mg, 90 mg, 130 mg (generic for Antara®)
 - FENOFIBRATE capsule 50 mg, 150 mg (generic for Lipofen®)
 - FENOFIBRATE capsule 67 mg, 134 mg, 200 mg (generic for Tricor®)
 - FENOFIBRATE tablet 40 mg, 120 mg (generic for Fenoglide®)
 - FENOFIBRIC acid delayed-release capsule 45 mg, 135 mg (generic for Trilipix®)
 - FENOFIBRIC acid tablet 35 mg, 105 mg (generic for Fibricor®)
 - FENOGLIDE tablet (fenofibrate)
 - LIPOFEN capsule (fenofibrate)
 - LOPID tablet (gemfibrozil)
 - TRICOR tablet (fenofibrate)
 - TRILIPIX capsule (fenofibric acid)

PREFERRED AGENTS with criteria**(Products denoted with ** have manually reviewed criteria, & products with ^^ have POS edits)**

- **ACL Inhibitor and ACL inhibitor/Cholesterol Absorption Inhibitor**
 - NONE
- **Apolipoprotein B Synthesis Inhibitor**
 - NONE
- **Omega-3 Fatty Acids**
 - OMEGA-3 ACID ETHYL ESTERS capsule (generic for Lovaza®)^{^^}
- **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor**
 - PRALUENT pen (alirocumab)^{**}
 - REPATHA syringe, autoinjector, pushtrex (evolocumab)^{**}
- **PCSK9-DIRECTED SMALL INTERFERING RNA (siRNA)**
 - NONE

NON-PREFERRED AGENTS with criteria**(Products denoted with ** have manually reviewed criteria.)**

- **ACL Inhibitor and ACL inhibitor/Cholesterol Absorption Inhibitor**
 - NEXLETOL tablet (bempedoic acid)^{**}
 - NEXLIZET tablet (bempedoic acid/ezetimibe)^{**}
- **Apolipoprotein B Synthesis Inhibitor**
 - JUXTAPID capsule (lomitapide)^{**}
- **Omega-3 Fatty Acids**
 - ICOSAPENT ETHYL capsule (generic for Vascepa®)^{**}
 - LOVAZA capsule (omega-3 acid ethyl esters)
 - VASCEPA capsule (icosapent ethyl)^{**}
- **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor**
 - NONE
- **PCSK9-Directed Small Interfering RNA (siRNA)**
 - LEQVIO syringe (inclisiran)^{**}

APPROVAL CRITERIA FOR PRALUENT AND REPATHA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have one of the following diagnoses (Any off-label requests will be reviewed on a case-by-case basis.)
 - Established cardiovascular disease and at risk for myocardial infarction, stroke, or unstable angina.
 - Primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH)
 - Homozygous familial hypercholesterolemia (HoFH)
- Beneficiary must have a trial and failure of ALL of the following:
 - High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40 mg) OR maximally tolerated statin therapy OR alternative dosing options to mitigate side effects unless a documented contraindication
 - Ezetimibe with statin therapy
- Compliance on previous lipid therapy is required unless contraindicated (defined as 90 out of 120 days). Beneficiary's Medicaid claims history will be consulted, and a pharmacy printout may be requested to ensure compliance

- Beneficiary should have an LDL-C \geq 70mg/dL and/or non-HDL-C \geq 100mg/dL after a compliant trial of moderate-high intensity statins and ezetimibe unless the beneficiary has a contraindication
- Prescriber must submit ALL of the following:
 - Current chart notes with documentation of previous treatments
 - Chart notes during trials of statins AND ezetimibe
 - Current labs including lipids as well as labs corresponding with previous trials of statins AND ezetimibe taken concomitantly
 - Diet plan for lowering cholesterol
- If beneficiary smokes, provider should submit a smoking cessation plan or documentation that the beneficiary has been counseled on smoking cessation
- Initial approval for 2 months

RENEWAL REQUIREMENTS FOR REPATHA OR PRALUENT:

- After initial approval, the beneficiary should demonstrate an improvement in the LDL-C levels
- Beneficiary must be compliant with therapy
- Renewals may be approved for 6 months with required response to therapy provided on each PA review
- Prescriber must submit ALL of the following:
 - Current chart notes
 - Current lipid panel

APPROVAL CRITERIA FOR LEQVIO:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), who require additional lowering of low-density lipoprotein cholesterol (LDL-C) OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have a trial and failure of ALL of the following:
 - High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40 mg) OR maximally tolerated statin therapy OR alternative dosing options to mitigate side effects unless a documented contraindication
 - Ezetimibe with statin therapy
 - Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent® or Repatha®)
- Beneficiary should have an LDL-C \geq 70mg/dL and/or non-HDL-C \geq 100mg/dL after a compliant trial (defined as 90 out of 120 days) of statins, ezetimibe, and PCSK9 inhibitors as defined above
- If approved, beneficiary must continue statin therapy at maximally tolerated dose
- Prescriber must submit ALL of the following:
 - Current chart notes with documentation of previous treatments
 - Current labs including lipids along with labs corresponding with previous trials of statin and ezetimibe used concomitantly and with the addition of a PCSK9 inhibitor
 - Treatment plan with goal LDL-C
 - Diet plan for lowering cholesterol
- If beneficiary smokes, provider should submit a smoking cessation plan or documentation that the beneficiary has been counseled on smoking cessation
- Initial approval for 3 months

RENEWAL REQUIREMENTS FOR LEQVIO:

- After initial approval, the beneficiary should demonstrate an improvement in the LDL-C levels
- Beneficiary must be compliant with therapy
- Renewals may be approved for 6 months with required response to therapy provided on each PA review
- Prescriber must submit ALL of the following:
 - Current chart notes

- Current lipid panel

APPROVAL CRITERIA FOR LOMITAPIDE MESYLATE (JUXTAPID)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with homozygous familial hypercholesterolemia (HoFH) and use this medication as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C)
- Beneficiary must have a trial and failure of ALL of the following:
 - High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40 mg) OR maximally tolerated statin therapy OR alternative dosing options to mitigate side effects unless a documented contraindication
 - Ezetimibe with statin therapy
 - Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent® or Repatha®)
- Prescriber must submit ALL of the following:
 - Current chart notes with documentation of previous treatments
 - Current labs including lipids along with labs corresponding with previous trials of statin and ezetimibe used concomitantly and with the addition of a PCSK9 inhibitor
 - Treatment plan with goal LDL-C
 - Diet plan for lowering cholesterol
 - Medical necessity over all other treatments for high cholesterol

RENEWAL REQUIREMENTS FOR JUXTAPID:

- After initial approval, the beneficiary should demonstrate an improvement in cholesterol levels
- Beneficiary must be compliant with therapy
- Renewals may be approved for 6 months with required response to therapy provided on each PA review
- Prescriber must submit ALL of the following:
 - Current chart notes
 - Current lipid panel

APPROVAL CRITERIA FOR BEMPEDOIC ACID (NEXLETOL/NEXLIZET):

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of heterozygous familial hypercholesterolemia or atherosclerotic cardiovascular disease who require additional lowering of LDL-C OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have a trial and failure of ALL of the following:
 - High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40 mg) OR maximally tolerated statin therapy OR alternative dosing options to mitigate side effects unless a documented contraindication
 - Ezetimibe with statin therapy
 - Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent® or Repatha®)
- Beneficiary should have an LDL-C \geq 70mg/dL and/or non-HDL-C \geq 100mg/dL after compliant trials (defined as 90 out of 120 days) of moderate-high intensity statins, ezetimibe, and PCSK9 inhibitors per current treatment guidelines unless the beneficiary has a contraindication
- Beneficiary must be prescribed concomitant statin therapy unless contraindicated or patient demonstrated statin intolerance
- Prescriber must submit ALL of the following:
 - Current chart notes with documentation of previous treatments

- Current labs including lipids along with labs corresponding with previous trials of statin and ezetimibe used concomitantly and with the addition of a PCSK9 inhibitor and uric acid levels for patients with a gout diagnosis
- Treatment plan with goal LDL-C
- Diet plan for lowering cholesterol
- Medical necessity over the use of medication outlined in current treatment guidelines
- If beneficiary smokes, provider should submit a smoking cessation plan or documentation that the beneficiary has been counseled on smoking cessation
- Initial approval for 2 months

RENEWAL REQUIREMENTS FOR NEXLETOL OR NEXLIZET:

- After initial approval, the beneficiary should demonstrate an improvement in the LDL-C levels
- Beneficiary must be compliant with therapy
- Renewals may be approved for 6 months with required response to therapy provided on each PA review
- Prescriber must submit ALL of the following:
 - Current chart notes
 - Current lipid panel

APPROVAL CRITERIA FOR OMEGA-3 ACID ETHYL ESTERS (LOVAZA)

APPROVAL CRITERIA FOR POS EDIT:

- Diagnosis in Medicaid medical history in previous 3 years of hypertriglyceridemia; AND
- Triglyceride level ≥ 500 mg/dL in the last 180 days; AND
- Beneficiary's Medicaid pharmacy drug history indicates at least three (3) claims of fibric acid derivatives in the last 365 days; AND
- Beneficiary's Medicaid pharmacy drug history indicates at least one (1) paid claim for one of the following in the past 14-60 days preferably containing a seven (7) day overlap with a fibric acid derivative:
 - Maximally tolerated statin dose
 - Ezetimibe

Manual review PA will be on a case-by-case basis if the above requirements are not found in the Medicaid system for POS approval. Prescribers must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

APPROVAL CRITERIA FOR ICOSAPENT ETHYL (VASCEPA)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must meet one of the following:
 - Use as an adjunct to maximally-tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride levels AND both of the following:
 - Laboratory documentation of fasting triglycerides ≥ 150 mg/dL and LDL-C ≤ 100 mg/dL
 - Must be diagnosed with either established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for CVD
 - Use as an adjunct to diet to reduce TG with severe (≥ 500 mg/dL) hypertriglyceridemia.
- Beneficiary must be compliant on a maximally tolerated statin therapy for at least 4 weeks
- Provider must submit ALL of the following:
 - Current chart notes with documentation of previous treatments
 - Current labs including lipids along with labs
 - Treatment plan with goal LDL-C and triglycerides

- Diet plan for lowering triglycerides
- Medical necessity over omega-3 acid ethyl esters and fibric acid agents

RENEWAL REQUIREMENTS FOR VASCEPA:

- After initial approval, the beneficiary should demonstrate an improvement in the triglyceride levels
- Beneficiary must be compliant with therapy
- Renewals may be approved for 6 months with required response to therapy provided on each PA review
- Prescriber must submit ALL of the following:
 - Current chart notes
 - Current lipid panel

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

EFFECTIVE IMMEDIATELY

1) SKYCLARYS™ (omaveloxolone) 50 mg capsule

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with Friedreich's ataxia confirmed by detection of a mutation of the FXN gene **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must exhibit clinical symptoms consistent with Friedreich's ataxia (e.g., muscle weakness, decline in coordination, frequent falling)
- Skyclarys™ is prescribed by a neurologist
- Beneficiary should not be approved or continue on this therapy with any of the following:
 - Severe hepatic impairment (Child-Pugh C); dosage adjustment for moderate hepatic impairment (Child-Pugh B)
 - Require treatment with a strong or moderate CYP3A4 inducer
 - Require treatment with a strong or moderate CYP3A4 inhibitor (may use concomitantly with a dose adjustment)
 - Consider discontinuation with signs and symptoms of fluid overload and/or heart failure
 - B-type Natriuretic Peptide (BNP) >200 pg/mL
- Prescriber must submit **ALL** of the following:
 - Current chart notes
 - Current labs including ALT, AST, bilirubin, B-type Natriuretic Peptide (BNP), and lipid parameters prior to initiating therapy (ALT, AST, bilirubin monthly for the first 3 months)
 - Specific symptoms associated with Friedreich's ataxia for this beneficiary as a baseline with a description concerning bulbar function, upper limb coordination, lower limb coordination, and upright stability
 - Genetic test results confirming the diagnosis

RENEWAL REQUIREMENTS:

- Prescriber must submit the following:
 - Current chart notes with documentation of current clinical presentation
 - Current labs (monitor every 3 months) including ALT, AST, and bilirubin
- Beneficiary must demonstrate an improvement or stabilization in clinical presentation compared to baseline
- Beneficiary must continue to meet approval criteria

QUANTITY EDITS:

90/ 30 days

EFFECTIVE IMMEDIATELY**2) VANFLYTA® (quizartinib) 17.7 mg and 26.5 mg tablet****APPROVAL CRITERIA:**

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with Acute Myeloid Leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiaries of reproductive potential (male or female) must use effective contraception
- Beneficiary should take VANFLYTA with standard chemotherapy during the induction (cytarabine and anthracycline) and consolidation (cytarabine) phase and as monotherapy during maintenance phase.
- Prescriber and pharmacy must be VANFLYTA REMS certified
- Beneficiary should not be approved or continue this therapy with any of the following:
 - Severe hypokalemia or hypomagnesemia
 - Long QT syndrome (QTcF interval > 450 ms at baseline), history of ventricular arrhythmias or history of torsades de pointes
 - Ordered as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT)—not indicated for this population
- Prescriber must submit **ALL** of the following:
 - Current chart notes
 - Documentation of previous failed therapies and current therapies
 - Current labs including potassium and magnesium
 - Current ECG report (also once weekly during induction and during early maintenance phase)
 - Test results confirming FLT3-ITD mutation positivity
 - Dose requested

RENEWAL REQUIREMENTS:

- Prescriber must submit the following:
 - Current chart notes
 - Current labs including potassium and magnesium
 - Current ECG report
 - Dose requested
- Beneficiary must continue to meet approval criteria

QUANTITY EDITS:

2 tablets per day

EFFECTIVE IMMEDIATELY**3) AKEEGA™ (niraparib tosylate monohydrate and abiraterone acetate) 100/500 mg or 50/500 mg tablet****APPROVAL CRITERIA:**

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with deleterious *BRCA*-mutated (*BRCAm*) metastatic castration-resistant prostate cancer **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.

- Beneficiary must either receive gonadotropin-releasing hormone (GnRH) analog concurrently or should have had a bilateral orchiectomy
- Beneficiary must be prescribed prednisone concomitantly
- Beneficiaries with female partners of reproductive potential should use effective contraception
- Beneficiary should not be approved or continue this therapy with any of the following:
 - Develops hypertensive crisis or severe cardiovascular adverse reactions
 - Moderate to severe hepatic impairment
 - Develop symptoms of posterior reversible encephalopathy syndrome (PRES)
 - Confirmed myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML)
 - Not prescribed concomitant GnRH analog or had a bilateral orchiectomy
- Prescriber must submit **ALL** of the following:
 - Current chart notes
 - Documentation of previous therapies tried
 - Genetic report documenting presence of BRCA mutation
 - Current labs including CBC, CMP, and LFTs

RENEWAL REQUIREMENTS:

- Prescriber must submit
 - Current chart notes with response to therapy
 - Current labs including CBC, CMP and LFTs
- Beneficiary does not develop denial criteria

QUANTITY EDITS:

#62/ 31 days

4) FRIENDLY REMINDERS

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

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

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.”

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

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

<https://humanservices.arkansas.gov/>

<https://humanservices.arkansas.gov/covid-19/dhs-response-to-covid-19/updates-for-providers/>

For adult vaccines (ages 18 and above), the following HCPCS and CPT codes are to be used in conjunction with the vaccine being administered:

G0008 – Influenza immunization

90471 – First vaccine administered
90472 – Subsequent vaccines administered

The injection administration code, **T1502**, will continue to be payable for beneficiaries of all ages. **T1502** may be used for billing the administration of subcutaneous and/or intramuscular injections only. If you have questions regarding this notice, please contact the Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at (501) 376-2211. Arkansas Medicaid provider manuals (including update transmittals), official notices, notices of rulemaking, and remittance advice (RA) messages are available for download from the Arkansas Medicaid website: <https://humanservices.arkansas.gov/divisions-shared-services/medical-services/>

If assistance is needed with a Medicaid vaccine or immunization billing issue, the MMIS outreach specialists are available to help. Please refer to this website to find the outreach/provider rep for your pharmacy: <https://afmc.org/health-care-professionals/arkansas-medicaid-providers/mmis-outreach-specialists/>

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. **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.**

6. **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://ar.magellanrx.com/provider-documents>

7. **HARD EDIT ON EARLY REFILL:**

Non-controlled drugs:

The hard edit disallowing early refills (ER) for non-controlled drugs sooner than 75% of days' supply expended was implemented on February 16, 2016. Pharmacies will no longer be able to override the ProDUR early refill edit to

refill non-controlled drugs sooner than 75% of the days' supply has elapsed. Refills for non-controlled drugs sooner than 75% of the days' supply elapsed will require a manual review PA, and the pharmacy or prescriber must provide documentation to Medicaid that the dose was increased during the month which caused the prescription to run out sooner than expected/calculated. The increased dose must be within the allowed Medicaid dose edits, or an approved PA must be in the system for the beneficiary for the higher dose or an early refill PA will not be approved.

Controlled drugs:

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

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

Non-controlled drugs:

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

Controlled drugs:

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

9. **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.

10. **ANTIPSYCHOTIC AGENT CRITERIA FOR CHILDREN:**

< 18 YEARS OF AGE:

Each new start of any antipsychotic agent for children < 18 years of age require a completed/signed informed consent form, current metabolic labs, and documentation of medical necessity with chart notes. Beneficiaries have an ongoing requirement for labs for metabolic monitoring every 6 months. When 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.

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

< 10 YEARS OF AGE:

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

11. **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.

- 12. ANY REIMBURSEMENT RATES STATED IN THIS MEMORANDUM (OR ANY PREVIOUS MEMORANDUMS) ARE FOR REFERENCE PURPOSES ONLY AND SUBJECT TO CHANGE:** AR Medicaid Pharmacy Program reimbursement methodology changed based on the requirements in the Affordable Care Act (ACA) and requirements of §447.502 of the final regulation and based on the CMS imposed final implementation date of April 1, 2017. The pricing methodology is lesser of methodology that applies to all brand or generic drugs for usual and customary charge, or NADAC, or ACA FUL, or SAAC. If the NADAC is not available, the allowed ingredient cost shall be WAC + 0%, SAAC, or ACA FUL. The Professional Dispensing Fee has been increased to \$9 for Brand Drugs and \$10.50 for Preferred Brand Drugs and all Generics. Reimbursement rates stated in this memo are in no way a contractual obligation by Arkansas Medicaid. NADAC pricing is subject to change and any pricing stated is only current as of the date this memo was drafted. Current Generic Upper Limits (GUL) or Maximum Allowable Cost (MAC) that have been issued at the State and or Federal level, along with State issued Capped Upper Limits (CAP), can be found on the Arkansas Medicaid website: <https://ar.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://ar.magellanrx.com/forms-documents>
- 13. OPIOID INFORMATION ON THE MAGELLAN WEBSITE:** To provide educational materials to prescribers and pharmacists on opioid dosing, opioid use disorder, medication assisted treatment and polypharmacy, an opioid information tab has been added to the Magellan Health website. <https://ar.magellanrx.com/provider-documents>
- 14. HEPATITIS C TREATMENT INFORMATION**
Educational information on treating Hepatitis C along with treatment consultations may be obtained through the Clinician Consultation Center.
- 1) Link for the Clinician Consultation Center—
<http://www.hepcap.org/hepatitis-c-consultation-warmline/>
 - 2) Hepatitis C Warmline for phone consultation—(844) HEP-INFO or (844) 437-4636

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

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

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

This advance notice 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.