

**Arkansas Medicaid Prescription Drug Program
Prior Authorization Criteria for Select Oncology Medications**

Drug/Drug Class:	Oncology Medication (pharmacy claim) designated with an asterisk* on the PA form
First Implementation Date:	Varies
Updated PDL:	N/A
Updated Criteria:	07/01/2024
Status Criteria:	<u>Criteria Revision</u> New Criteria

NOTE: New-to-market oncology medications will follow the **Pharmacy Oncology Drug Management Policy** unless reviewed by the Drug Utilization Review (DUR) Board for specific criteria. If specific criteria has been DUR Board approved, this memo will be updated to include that information.

POINT-OF-SALE EDITS—if criteria is met, no prior authorization request will be needed.

- **ARIMIDEX® (anastrozole)**
 - Medical history for female with breast cancer billed in the past 3 years
 - Claim will deny if a diagnosis of infertility is found in Medicaid history
- **FEMARA® (letrozole)**
 - Medical history for female with breast cancer billed in the past 3 years
 - Claim will deny if a diagnosis of infertility is found in Medicaid history

PRIOR AUTHORIZATION CRITERIA

- The following medications have specific criteria as approved by the Arkansas Medicaid Drug Utilization Review (DUR) Board/ Drug Review Committee (DRC).
- The Oncology Medicaid Prior Authorization Fax Form must be completed. [Forms & Documents - Arkansas \(primetherapeutics.com\)](#)

1. KOSELUGO (selumetinib) 10 mg and 25 mg capsules (Effective 7/15/2020)

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN) **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 at least one measurable PN measuring at least 3 cm AND either a positive genetic test for NF1 **OR** have at least one other diagnostic criterion listed below:
 - 6 or more café-au-lait macules; OR
 - Freckling in axilla or groin; OR

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- Optic glioma; OR
- 2 or more Lisch nodules; OR
- Distinctive bony lesion; OR
- First-degree relative with NF1
- Beneficiary should not be approved or continue this therapy with any of the following:
 - Does not meet approval criteria
 - If approved, beneficiary has disease progression or unacceptable toxicity and is unable to tolerate 2 dose reductions
 - Unable to swallow a whole capsule
 - BSA is $< 0.55\text{m}^2$
 - Has retinal vein occlusion
 - Has symptomatic or Grade 3 or 4 decreased LVEF
 - Has Grade 4 diarrhea or Grade 3 or 4 colitis
 - Has rhabdomyolysis
 - Has severe hepatic impairment (Child-Pugh C)
 - Is pregnant
 - Is not using birth control when has reproductive potential
 - Requires strong or moderate CYP3A4 inducers
 - Dose should be reduced for required concomitant strong or moderate CYP3A4 inhibitors
- Provider should submit the following:
 - Current chart notes with status of plexiform neurofibromas
 - Current baseline left ventricular ejection fraction (LVEF)
 - Documentation of comprehensive ophthalmic assessment
 - Current labs including serum CPK, baseline INR, CBC, and LFTs
 - $\text{ANC} \geq 1500/\mu\text{L}$
 - $\text{Hemoglobin} \geq 9\text{g/dl}$
 - $\text{Platelets} \geq 100,000/\mu\text{L}$
 - Current body surface area (BSA)—no recommended dosage for recipients with $\text{BSA} < 0.55\text{m}^2$
 - Prescriber should provide plan for monitoring patients that require coadministration with vitamin-K antagonists or platelet antagonists
- Initial PA for 3 months

RENEWAL REQUIREMENTS

- Provider should submit the following:
 - Documentation of ejection fraction assessed every 3 months for the first year
 - Documentation of current labs including serum CPK, INR, CBC and LFTs
 - Current chart notes with documentation of response to therapy
 - Documentation of current BSA
 - Current required dosage
- Beneficiary should continue contraception unless has no reproductive potential
- Beneficiary should show improvement with the plexiform neurofibromas.

QUANTITY EDITS

- 10 mg capsule — #270/30 days
 - 25 mg capsule — #120/30 days
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2. REZUROCK (belumosudil) 200 mg tablet (Effective 10/20/2021)

APPROVAL CRITERIA

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary of reproductive potential should use effective contraception
- Beneficiary should not be approved or continue this therapy with any of the following:
 - Does not meet approval criteria
 - Is pregnant
 - If approved, demonstrates disease progression
 - Develops hepatotoxicity while on the medication with either Grade 4 AST or ALT (20X ULN) or Grade 3 or 4 bilirubin (3X ULN)
 - Has the following baseline labs
 - Platelets < 50 X 10⁹ /L
 - ANC < 1.5 X 10⁹ /L
 - AST or ALT > 3X ULN
 - Total bilirubin > 1.5X ULN
 - eGFR < 30 mL/min/1.73m²
 - FEV1 ≤ 39% (patients with pulmonary manifestations)
- Prescriber must submit the following:
 - Current chart notes
 - Documentation of previous therapies tried with response
 - Current labs including CBC with differential, LFTs, and CMP
 - Negative pregnancy test for female recipient of reproductive potential

RENEWAL REQUIREMENTS

- Beneficiary demonstrates an improvement in baseline symptoms associated with GVHD
- Prescriber must submit the following:
 - Current chart notes
 - Response to treatment
 - Current labs including CBC with differential, LFTs, and CMP

QUANTITY EDITS:

- #30/ 30 days
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3. TURALIO (pexidartinib) 125 mg capsule (Effective 10/16/2019)

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary has a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) (also known as pigmented villonodular synovitis (PVNS) and giant cell tumor of the tendon sheath (GCT- TS)) associated with severe morbidity or functional limitations and not amenable to improvement with surgery **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Provider and beneficiary must be enrolled in REMS program
- Beneficiary should not be approved or continue this therapy with any of the following:
 - Does not meet approval criteria
 - Is pregnant or breastfeeding
 - If cannot tolerate dose of 200 mg twice daily
 - Develops hepatotoxicity
 - ALT and/or AST >10 x ULN
 - ALP and GGT >2 x ULN
 - Total bilirubin \geq 2 x ULN or Direct bilirubin >1.5 x ULN
 - Requires concomitant proton pump inhibitors
 - Requires concomitant strong CYP3A inhibitor (e.g., itraconazole) or uridine diphosphoglucuronosyltransferase (UGT) inhibitor (e.g., probenecid)—if unavoidable, reduce Turalio® dose
 - Has active or chronic infection with hepatitis C virus, hepatitis B virus or human immunodeficiency virus
- Provider must submit the following:
 - Current chart notes with description of current range of motion and treatment history (if applicable)
 - MRI results confirming diagnosis
 - Medical necessity of Turalio® over surgery and/or radiation
 - Current labs
 - LFTs including ALT/AST, ALP, GGT and bilirubin (labs monitored weekly for first 8 weeks, every 2 weeks for the next month and every 3 months thereafter)
 - Renal function including serum creatinine and BUN
 - CBC with differential
 - Documentation of stable prescription of analgesic regimen which can include opioids, anti-inflammatory medications or corticosteroids for at least 2 weeks with continued pain and mobility difficulties
 - Attestation that provider counseled sexually active patients (male and female) that are not surgically sterile to use condoms or other forms of birth control
 - Physical therapy notes if available; if not receiving PT, provider should explain rationale
- PA's approved month-to-month for at least first 3 months to monitor labs

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RENEWAL REQUIREMENTS

- Beneficiary is compliant on therapy

- Prescriber must submit the following:
 - Current chart notes
 - Current labs including LFTs, CBC with differential and renal function which must fall within manufacturer's guidelines for renewal
 - Documentation of response to therapy with decrease in tumor size and/or documentation of improvement in range of motion
 - Reevaluation for surgery eligibility.

QUANTITY EDITS:

- #120 per 30 days
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DATE:	SUMMARY OF CHANGES:	UPDATED BY:
07/01/2024	DUR BOARD REVIEW FOR ONCOLOGY MED SUMMARY	DUR BOARD