P.O. Box 25010
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Manual Review Criteria
Reference Number: ARTC.PHAR.501
Last Review Date: 06/24

Revision Log

Description
This policy provides criteria to use for reviewing requests designated as manual review on the state website when there are no drug-specific criteria provided. Additionally, these criteria may be used to determine medical necessity for drugs requiring prior authorization (PA) when drug-specific criteria is not available.

Policy
I. Initial Approval Criteria

1. Requested indication is consistent with FDA-labeling, approved compendia (NCCN, etc.), and/or current clinical practice guidelines. Indication has been confirmed by laboratory testing, if laboratory testing exists as the standard for diagnosis AND
2. Member has a medical reason supported by documentation for not using PDL alternatives or alternatives that would be appropriate based on current clinical practice/guidelines that do not require a PA with Arkansas Medicaid (see state memos), when such agents exist AND
3. Medication meets Claim Edits for age/gender/dose/quantity/cumulative quantity OR
   For non-topicals: if requesting outside of the claim edits, the requested medication meets FDA-labeling, compendium support, or has been studied and found to be safe and effective for the exception to the claim edit being requested OR
   For topicals: if requesting outside of the quantity edits, the quantity must be consistent with what is needed per BSA calculations for the area being treated.
4. If request is for combination product or alternative dosage form or strength of existing drugs, medical justification supports inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products) AND
5. Treatment is not for a benefit-excluded use (see Exclusions on Work Instructions) AND
6. Member has no contraindications to the prescribed agent per the product information label

Approval duration: Duration of request or 6 months (whichever is less)

II. Continued Therapy

1. Currently receiving medication via Centene benefit or Arkansas Medicaid benefit AND
2. Member has previously met initial approval criteria for diagnosis and clinical edits being requested AND
3. Member is responding positively to therapy.

Approval duration: Duration of request or 12 months (whichever is less)

III. Oncology Specific Review.

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This policy outlines the prior authorization review process for oncology drugs covered under the pharmacy benefit for Arkansas Total Care.

1. Prior authorization criteria for oncology drugs covered under this policy will be based on the FDA approved label and support found in the NCCN treatment guidelines with NCCN level of evidence 1 or 2a unless otherwise noted. See the prior authorization (PA) form for specifics on exceptions.
2. Certain medications follow state DUR Board approved criteria found in the State PA Criteria Document. State PA Criteria Document. Arimidex® (anastrazole) and Femara® (letrozole) will process at point-of-sale without a prior authorization if the beneficiary's medical history includes a female with breast cancer billed in the last 3 years.
3. Requests for an indication, dosage, age, or duration of treatment outside of the FDA approved label and NCCN treatment recommendations are considered off-label.
4. All prior authorization requests must be submitted by or in consultation with an oncologist or hematologist.
5. Documentation supporting the prior authorization request must be submitted at the time of the request.
6. Quantity limits apply to all medications based on FDA-approved dosing.
7. When submitting an initial prior authorization request for an oncology product, providing all pertinent information with the initial request will expedite reviews. At a minimum, the prescriber must submit:
    a. Current chart notes
    b. Type of cancer with documentation of any mutations
    c. All previous therapies tried with timelines and response (i.e., medications and surgeries)
    d. Current labs specific to the type of cancer and treatment requesting (e.g., complete blood count, renal function labs, liver function panel, etc.)
    e. Specific imaging requirements per the package insert (e.g., MRI or CT imaging)
    f. Letter of medical necessity outlining the rationale for the treatment requested especially if the request is off-label
    g. Current weight or body surface area
    h. Dose requested
    i. Pregnancy test results if recommended in the package insert
    j. ECOG performance status score and medical necessity of treatment with ECOG score of 4
8. For prior authorization renewal requests, the prescriber must submit the following:
    a. Current chart notes
    b. Current lab work
    c. Current weight or body surface area
    d. Dose requested
    e. Documentation of current response to treatment
    f. Attestation that the patient exhibits a positive response from treatment without intolerable side effects

Approval Duration: Initial Requests may be approved for 3 months. Renewals may be approved for 3-6 months depending on the level of monitoring required for the treatment.

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References
AR FFS Medicaid Pharmacy Oncology Drug Management Policy
Arkansas Medicaid Prescription Drug Program Oncology Medication Prior Authorization Fax Form

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed	03/20	07/20
Annual review, no changes		07/21
Annual Review; updated policy description	7/22	07/25/22
Annual Review; no changes.	7/23	07/24/23
Annual Review; Updates to include oncology.	6/24	07/30/24