Original Effective Date: 01/01/2024
Current Effective Date: 01/01/2024
Last P&T Approval/Version: NA
Last Reviewed Date: 10/2023
Policy Number: C26331-A

Medical Necessity Review Nebraska 599 CHIP ONLY

PRODUCTS AFFECTED

Non-Preferred Products, Non-Formulary Products, Preferred Products requiring a medical necessity review or quantity limit

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
NA

REQUIRED MEDICAL INFORMATION:
NOTE: PRIOR TO ANY REVIEW FOR EXCEPTION, REVIEWER SHOULD VERIFY THERAPY ELIGIBILITY FOR BENEFIT EXCLUSION OR CARVE OUT STATUS
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. REQUEST FOR COVERAGE OF DRUG PRODUCT REQUIRING A MEDICAL NECESSITY REVIEW:

1. The requested agent is being used to support the pregnant woman's unborn child that is not otherwise excluded from coverage (i.e., recognized as a covered benefit by the applicable health plan's program)
   AND
2. Requested medication has met any applicable utilization management requirements if they are in the same therapeutic class as formulary medications that require such authorization
   OR
3. (a) Requested drug has been approved by the U.S. Food and Drug Administration (FDA) for at least ONE indication
   AND
   (b) i. Requested drug is being used for an FDA-approved indication
   OR
   ii. Requested drug is being used for a medically accepted indication that is supported by information from the appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.)
   AND
   (c) Age of the pregnant woman carrying the unborn child is within FDA labeling limits, compendia supported age range, and/or guideline recommendations for the diagnosis
   AND
   (d) Requested dosing is consistent with the FDA labeling or compendia supported dosing for both individual dose and requested frequency AND does not exceed the maximum recommended dosing of the FDA label or compendia
   AND
   (e) Prescriber attests that pregnant woman carrying the unborn child has no contraindications for use of the requested product, based on contraindications specified on FDA labeling
   AND
4. IF THIS IS A NON-PREFERRED/NON-FORMULARY PRODUCT:
   a. Pregnant woman carrying the unborn child has tried, failed, or had serious side effects to the specified number of preferred products within the same class
      OR
   b. Pregnant woman carrying the unborn child requires use of a specific dosage form (e.g., suspension, solution, injection) that is not available as the formulary alternatives
      OR
   c. Pregnant woman carrying the unborn child has a clinical condition which the listed formulary alternatives are not recommended based on published guidelines or clinical literature
      OR
   d. Pregnant woman carrying the unborn child had an adverse reaction to OR would be reasonably expected to have an adverse reaction to the listed formulary alternatives
      OR
   e. Pregnant woman carrying the unborn child has an FDA labeled contraindication to the listed formulary alternatives

   AND
5. Prescriber must submit pregnant woman's medical records and other relevant documentation as deemed necessary by Molina Healthcare to determine if a medical necessity use is reasonable and necessary for treatment used to support the pregnant woman's unborn child

B. DOSE LIMIT/QUANTITY LIMIT:

An exception may be granted for increased quantity of a drug on the formulary or the number of doses available under a dose restriction for the prescription formulary drug if:

1. The requested agent is being used to support the pregnant woman's unborn child that is not otherwise excluded from coverage (i.e., recognized as a covered benefit by the applicable health plan's program)

AND

2. (a) Requested drug is being used for an FDA-approved indication
   OR
   (b) Requested drug is being used for a medically accepted indication that is supported by information from the appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.)
   AND
3. The maximum allowed dose or frequency has been ineffective in the treatment used to support the pregnant woman's unborn child
   AND
4. (a) The requested dose and/or dosing frequency cannot be made with a higher strength and fewer dosages per day.
   OR
   (b) Prescriber attests that the pregnant woman carrying the unborn child requires a higher quantity with a lower dose for titration, therapy adjustments, dose alternating schedules, or to accommodate pregnant woman carrying the unborn child swallowing issues. [treatment plan must be provided for titration/dosage adjustment needs]
   OR
   (c) The prescriber attests that the toxicity risk is not greater than the probable benefit, and there is a specific lab measurement showing inadequate dosing, or there is reasonable clinical rationale to suggest inadequate absorption, or there is reasonable clinical rationale to suggest more rapid metabolism of the drug.
   AND
5. FOR REQUESTS GREATER THAN THE FDA LABELED LIMIT: Documentation of a detailed description of reason why the pregnant woman carrying the unborn child needs a greater quantity or dose greater than what the FDA recommends.
   NOTE: Review the maximum recommended dose per prescribing literature.

CONTINUATION OF THERAPY:
NA

DURATION OF APPROVAL:
Initial authorization: Estimated date of delivery, Continuation of Therapy: NA

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
Must be prescribed within FDA labeled or compendia supported age maximums or minimums

QUANTITY:
Must be prescribed within FDA labeled, compendia supported, or guideline recommended dosing maximums
MOLINA REVIEWER NOTE: Additional daily quantity limits may apply per formulary allowance

PLACE OF ADMINISTRATION:
N/A

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
N/A

DRUG CLASS:
N/A

FDA-APPROVED USES:
N/A

COMPENDIAL APPROVED OFF-LABELED USES:
NA

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
599 CHIP: Medical Coverage for Unborn Children

What is 599 CHIP?
The 599 CHIP program is designed for unborn children of pregnant women who are otherwise ineligible for coverage under Medicaid or CHIP.

This program is not full Medicaid coverage and only applies to prenatal care and pregnancy-related services.
These services are connected to the health of the unborn child, including labor and delivery.

Medications and vaccines that have not received final FDA marketing approval for any indication are considered investigational. Orphan designation is not synonymous to FDA-approval and orphan drug status has no significance in the evaluation of off-label treatments. An orphan drug is one that is used for the treatment of a rare disease or condition that either occurs in fewer than 200,000 individuals in the US or is more prevalent but for which there is no reasonable expectation that the cost of developing and marketing the drug in the US for such disease or condition would be recovered from US sales. The orphan drug designation is independent from marketing approval status and may apply to medications that are either approved or unapproved for marketing.

The following are currently the authoritative compendia for CMS approved clinical decision support tools to determine medically accepted indication of medical necessity:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Micromedex DrugDex Compendium (DrugDex) [Successor to USP-DI]
- Elsevier Gold Standard's Clinical Pharmacology Compendium (Clinical Pharmacology)
- Wolters Kluwer Lexi-Drugs (Lexi-Drugs)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
Coverage will not be authorized for medical necessity usage unless prior authorization request meets ALL criteria defined in the above section. Drugs are not covered when the following circumstances are applicable:

- The FDA has determined its use to be contraindicated; or
- The benefit plan excludes drug coverage; or
- The benefit plan includes drug benefit limitations based on a formulary and the off-label drug is not part of the formulary; or
- Pharmaceutical agents (and vaccines) that have not received final FDA marketing approval

for any indication or has not been fully licensed or approved by the FDA are considered investigational and coverage will not be authorized; or

- Use is identified as not indicated by CMS (in the case of Medicare members) or the FDA; or
- Use is specifically identified as not indicated in at least one of the major compendia; or
- Use is determined (based on peer-reviewed literature) that the drug is not safe and effective
- Expanded Access Program (EAP) (also referred to as 'Managed Access Program (MAP), Early Access Program, or Compassionate Use Program (CUP'): A pathway for physicians and patients with an immediately life-threatening condition or serious disease or condition to gain access to pre-approval, investigational product* outside of the clinical trial setting: The investigational drug, cost of the treatment(s) or procedure(s) the clinical trial is investigating, or procedure(s) required to collect data for the study will not be authorized.
- Drugs determined to be lacking substantial evidence of effectiveness based on DESI (Drug Efficacy Study Implementation) review.

OTHER SPECIAL CONSIDERATIONS:
N/A

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

REFERENCES

1. 599 CHIP Medical Coverage for Unborn Children: Department of Health and Human Services Nebraska Medicaid & Long-Term Care. Available at: https://dhhs.ne.gov/Documents/599%20CHIP%20one-pager.pdf. (Accessed: 09 October 2023).
2. Request for Proposal for Contractual Services: State of Nebraska Department of Health and Human Services. Release Date: April 15, 2022. Last Updated: July 1, 2019. Available at: https://dhhs.ne.gov/Pages/Grants-and-Contract-Opportunities.aspx.
3. NE Medicaid Provider Manual. Molina Healthcare of Nebraska, Inc. Last Updated: August 14, 2023. Available at: http://www.molinahealthcare.com/.
4. MHI PHARM 008.1 Medication Prior Authorization NE Addendum. Molina Healthcare of Nebraska, Inc. Last Updated: June 30, 2023.
5. Nebraska Department of Health and Human Services (DHHS) Prior Authorization Criteria for Documentation of Medical Necessity for Quantity Limit or High Dose Override. Revised: October 1, 2012. Available at: https://nebraska.fhsc.com/priorauth/paforms.asp.

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q4 2023