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Policy Number: C10169-A

Global Formulary Exception Criteria (NF, QL, ST, etc.)

PRODUCTS AFFECTED

Non-Formulary Products, Formulary Products requiring a medical necessity review, Step therapy, Age limit, Quantity limit, New to Market Launched drugs

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:
Per FDA label or compendia support for the requested product

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. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. REQUEST FOR COVERAGE OF A DRUG NOT ON FORMULARY:

Molina Reviewer Note: This criteria should only be used in the absence of drug/drug class specific Molina Healthcare Inc. Prior Authorization Criteria or Medical Clinical Policy (MCP).

1. The requested agent is being used to treat a medical condition/disease state that is not otherwise excluded from coverage (i.e., recognized as a covered benefit by the applicable health plan's program)
   MOLINA REVIEWER NOTE: For Illinois Marketplace, New Mexico Marketplace, New York Marketplace, Ohio Marketplace, and New York Medicaid, please see Appendix.
   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.)
   NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy
   AND
3. FOR NEW TO MARKET PRODUCT (LAUNCHED WITHIN LAST 180 DAYS): Medications being considered for a formulary exception must meet any applicable utilization management requirements if they are in the same therapeutic class as formulary medications that require such authorization
   AND
4. (a) Documentation member has trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).
   MOLINA REVIEWER NOTE: For Illinois Marketplace and Nevada Marketplace, please see Appendix.
   OR
   (b) Member requires use of a specific dosage form (e.g., suspension, solution, injection) that is not available as the formulary alternatives
   OR
   (c) Member has a clinical condition for which the listed formulary alternatives are not recommended based on published guidelines or clinical literature.
   OR
   (d) Member had an adverse reaction to OR would be reasonably expected to have an adverse reaction to the listed formulary alternatives
   OR
   (e) Member has an FDA labeled contraindication to the listed formulary alternatives

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 treat a medical condition/disease state that is not otherwise excluded from coverage (i.e., recognized as a covered benefit by the applicable health plan's program)
   MOLINA REVIEWER NOTE: For Illinois Marketplace, New Mexico Marketplace, New York Marketplace, Ohio Marketplace, and New York Medicaid, please see Appendix.
   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.)
   NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy
   AND
3. The maximum allowed dose or frequency has been ineffective in the treatment of the member's disease or medical condition

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 member requires a higher quantity with a lower dose for titration, therapy adjustments, dose alternating schedules, or to accommodate member swallowing issues. [treatment plan must be provided for titration/dosage adjustment needs]
   OR
   (c) The prescriber attest 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. If the dose and/or frequency of dosing being requested is greater than the FDA labeled or compendia supported dosage, please refer to the Off-Label Use of Drugs and Biologic Agents policy for review.
   AND
6. FOR TOPICAL DOSAGE FORMS: Documentation of area and/or size of application site and application frequency (see appendix).

C. STEP THERAPY FOR FORMULARY DRUGS:
   MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.
   1. The requested agent is being used to treat a medical condition/disease state that is not otherwise excluded from coverage (i.e., recognized as a covered benefit by the applicable health plan's program)
      MOLINA REVIEWER NOTE: For Illinois Marketplace, New Mexico Marketplace, New York Marketplace, Ohio Marketplace, and New York Medicaid, please see Appendix.
      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.)
      NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy
      AND
   3. Documentation or prescriber attestation that the step one agent(s) (i.e., preferred products) have been ineffective in the treatment of the member's disease or medical condition OR based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the member, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or member compliance
      MOLINA REVIEWER NOTE: For Nevada Marketplace, please see Appendix.
      OR
   4. Documentation or prescriber attestation that the preferred product has caused or based on sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the member, and known characteristics of the drug regimen, is likely to cause a clinically significant adverse reaction or other harm to the member and which the requested drug is not as likely to cause.
      NOTE: FOR CA/FL/KY/WA MARKETPLACE: Approval letter or other coverage documentation showing the formulary drug we require step therapy for was covered for the member by their previous insurer will also meet this criteria.

D. BRAND EXCLUSION/GENERIC REQUIREMENT:
   1. The requested therapy is a BRAND product with a generic or authorized generic available
      AND
   2. (a) Documentation that the member has been re-challenged on a maximum of three available

generically manufactured products OR, if three generic manufacturers are not available, other generically available products within the same therapeutic class (three total generic products)
MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.
OR
(b) Documentation the member experiences a documented adverse drug reaction with the generic agent re-challenge (examples: rash, anaphylaxis) that is NOT a known side effect of the medication and/or the prescriber has submitted a completed FDA MedWatch form [DOCUMENTATION REQUIRED]
OR
(c) Drug requested is a Narrow Therapeutic Index medication

E. FORMULARY DRUGS WITH MEDICAL NECESSITY/PRIOR AUTHORIZATION REVIEW REQUIRED:
MOLINA REVIEWER NOTE: This criteria should only be used in the absence of drug/drug class specific Molina Healthcare Inc. Prior Authorization Criteria or Medical Clinical Policy (MCP).

1. The requested agent is being used to treat a medical condition/disease state that is not otherwise excluded from coverage (i.e., recognized as a covered benefit by the applicable health plan's program)
   MOLINA REVIEWER NOTE: For Illinois Marketplace, New Mexico Marketplace, New York Marketplace, Ohio Marketplace, and New York Medicaid, please see Appendix.
   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.)
   NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy
   AND
3. (a) Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).
   MOLINA REVIEWER NOTE: For Illinois Marketplace and Nevada Marketplace, please see Appendix.
   OR
   (b) Documentation that formulary agents with the same indication, based on sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the member, and known characteristics of the drug regimen, are likely to be ineffective or adversely affect the drug's effectiveness or member compliance.
   AND
4. Requested drug therapy is consistent with the diagnosis and treatment of a condition, the standards of good medical practice and required for other than convenience

F. AGE LIMIT:

1. The requested agent is being used to treat a medical condition/disease state that is not otherwise excluded from coverage (i.e., recognized as a covered benefit by the applicable health plan's program)
   MOLINA REVIEWER NOTE: For Illinois Marketplace, New Mexico Marketplace, New York Marketplace, Ohio Marketplace, and New York Medicaid, please see Appendix.
   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.)
   NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy

AND

3. Use for the member's age for the requested indication is FDA labeled or supported by the appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.)
   AND
4. If the member age and indication being requested is not found in the FDA label or appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.), please refer to the Off-Label Use of Drugs and Biologic Agents policy for review.
   AND
5. FOR LIQUID DOSAGE FORM REQUESTS: Documentation member is unable to ingest preferred solid dosage form (i.e., tablet or capsule) due to ONE of the following: age, oral/motor difficulties, dysphagia, or member utilizes a feeding tube for medical administration.

G. FOR NEW MOLINA MEMBER:
[IF NON-FORMULARY OR NON-PREFERRED DRUG IS BEING REQUESTED (NOT ON THE PDL AS OF REQUEST DATE): Member must meet the Molina continuation of therapy exception policy unless otherwise specified per applicable state regulations]

1. Member must meet ALL of the following:
   (a) The requested Non-Formulary or Non-Preferred drug is not excluded from coverage (e.g., drugs for weight loss, drugs for erectile dysfunction) ***SSA Section 1927d (2) List of Drugs subject to restriction
   MOLINA REVIEWER NOTE: For Illinois Marketplace, New Mexico Marketplace, New York Marketplace, Ohio Marketplace, and New York Medicaid, please see Appendix.
   AND
   (b) The requested Non-Formulary or Non-Preferred drug is prescribed for a medically accepted indication as defined in Sec. 1927 of the Social Security Act: Permissible Restrictions
   AND
   (c) The member has been treated with the requested Non-Formulary or Non-Preferred drug at a stable, FDA labeled dosage for at least 90 days and the prescriber indicates (orally or in writing) that the prescribed medication will best treat the member's condition
   AND
   (d) The pharmacy or prescriber must provide an attestation that the medication was covered by another payer and not obtained via cash pay, drug manufacturer-issued debit cards, or via free goods/pharmaceutical samples. NOTE: The use of free goods or pharmaceutical samples will not be considered as meeting the 90-day treatment requirement for Continuation of Therapy overrides. A member, after meeting all conditions for cash pay, must pay for the entire cost of the non-covered prescription.
   NOTE: Continuation of Therapy override may be approved for up to 90 days, unless otherwise stated above. After 90 days, the prescriber must obtain prior authorization for the Non-Formulary or Non-Preferred drug or transition the member to an alternative therapy. Multiple Continuation of Therapy overrides will not be approved for the same drug.
   OR
2. Member is newly eligible to Molina Healthcare (within the last 30 calendar days) and there is a request for a medication **in which not enough information was made available** to make a clinical determination; a denial will be issued with a point-of-sale claim allowance (i.e., override) of 90 days ONLY for the following critical medication(s) or medication classes that could potentially lead to patient harm if access is not readily available.
   (a) Epinephrine
   (b) Glucagon
   (c) Antibiotics
   (d) Insulin
   (e) Anti-rejection
   (f) Anti-convulsant
   (g) Narcan
   (h) HIV agents
   (i) COPD/Asthma

(j) Anti-arrhythmic
(k) Mental Health
(l) Anticoagulant
(m) Specialty drug
NOTE: This is not a criterion for approval for medical necessity. This is an operational allowance until medical necessity can be determined.
OR

3. If the member has received a prescribed drug to treat a mental illness or emotional disturbance the member may continue to receive coverage for such prescribed drugs for up to one year
OR
4. Member is currently receiving a non-preferred therapy to treat an acute condition, defined as less than 60 days of treatment remain (i.e., antibiotic, antiviral therapy), therapy will be authorized up to 60 days or expected end of therapy, whichever is shorter
OR
5. Documentation is provided that the member has an existing approved prior authorization (PA) for the nonpreferred or restricted drugs, then the member's previously approved PA will be approved until the previous PA authorization expiration date

CONTINUATION OF THERAPY:
A. RENEWAL OF A PREVIOUS MOLINA AUTHORIZATION FOR ANY FORMULARY EXCEPTION TYPE (Excludes step therapy):

1. If the initial review was done for a new to market product that has since been P&T reviewed, please check for updated drug specific criteria
AND
2. Documentation of positive clinical response as demonstrated by low disease activity, stable disease, and/or improvements in the condition's signs and symptoms
AND
3. FOR THERAPIES TO TREAT CHRONIC CONDITIONS: Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:
Initial authorization: 12 months**;** New to Market Drug (launched within last 180 days): 3 months
Continuation of Therapy: 12 months
MOLINA REVIEWER NOTE: For Texas Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:
None

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

QUANTITY:
Must be prescribed within FDA labeled or compendia supported dosing maximums

PLACE OF ADMINISTRATION:
NA

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral, Topical, IM/ Subcutaneous

DRUG CLASS:
NA

FDA-APPROVED USES:
NA

COMPENDIAL APPROVED OFF-LABELED USES:
NA

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Illinois (Source: Illinois)
Ill. Rev. Stat. Ch. 215, § 5/356m Infertility Coverage "(d) A policy, contract, or certificate *may not impose any exclusions, limitations, or other restrictions on coverage of fertility medications that are different from those imposed on any other prescription medications*, nor may it impose any exclusions, limitations, or other restrictions on coverage of any fertility services based on a covered individual's participation in fertility services provided by or to a third party, nor may it impose deductibles, copayments, coinsurance, benefit maximums, waiting periods, or any other limitations on coverage for the diagnosis of infertility, treatment for infertility, and standard fertility preservation services, except as provided in this Section, that are different from those imposed upon benefits for services not related to infertility."
MOLINA REVIEWER NOTE: Clomiphene is on formulary.

Illinois (Source: Illinois General Assembly)
(215 ILCS 134/10) Sec. 10. Definitions. In this Act:
"Step therapy requirement" means a utilization review or formulary requirement that specifies, as a condition of coverage under a health care plan, the order in which certain health care services must be used to treat or manage an enrollee's health condition. "Step therapy requirement" does not include: (1) utilization review to identify when a treatment or health care service is contraindicated or clinically appropriate or to limit quantity or dosage for an enrollee based on utilization review criteria consistent with generally accepted standards of care developed in accordance with Section 87 of this Act; (2) the removal of a drug from a formulary or changing the drug's preferred or cost-sharing tier to higher cost sharing; (3) use of the medical exceptions process under Section 45.1 of this Act; any decision during a medical exceptions process based on cost is step therapy and prohibited; (4) a requirement to obtain prior authorization for the requested treatment; or (5) for health care plans operated or overseen by the Department of Healthcare and Family Services, including Medicaid managed care plans, any utilization controls mandated by 42 CFR 456.703 or a preferred drug list as described in Section 5-30.14 of the Illinois Public Aid Code.
(215 ILCS 5/155.37) Sec. 155.37. Drug formulary; notice. … (c) No formulary may establish a step therapy requirement as prohibited by Section 87 of the Managed Care Reform and Patient Rights Act.

Illinois (Source: Illinois General Assembly)
"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health

plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

Nevada (Source: Nevada Legislature)

"Chapter 689A of Nevada Revised Statutes (NRS) is hereby amended by adding thereto a new section to read as follows:

1. A policy of health insurance which provides coverage for prescription drugs must not require an insured to submit to a step therapy protocol before covering a drug approved by the Food and Drug Administration that is prescribed to treat a psychiatric condition of the insured, if:
    a. The drug has been approved by the Food and Drug Administration with indications for the psychiatric condition of the insured or the use of the drug to treat that psychiatric condition is otherwise supported by medical or scientific evidence;
    b. The drug is prescribed by:
        i. A psychiatrist
        ii. A physician assistant under the supervision of a psychiatrist;
        iii. An advanced practice registered nurse who has the psychiatric training and experience prescribed by the State Board of Nursing pursuant to NRS 632.120; or
        iv. A primary care provider that is providing care to an insured in consultation with a practitioner listed in subparagraph (1), (2) or (3), if the closest practitioner listed in subparagraph (1), (2) or (3) who participates in the network plan of the insurer is located 60 miles or more from the residence of the insured; and
    c. The practitioner listed in paragraph (b) who prescribed the drug knows, based on the medical history of the insured, or reasonably expects each alternative drug that is required to be used earlier in the step therapy protocol to be ineffective at treating the psychiatric condition…

3. As used in this section:
    c. *'Step therapy protocol' means a procedure that requires an insured to use a prescription drug or sequence of prescription drugs other than a drug that a practitioner recommends for treatment of a psychiatric condition of the insured before his or her policy of health insurance provides coverage for the recommended drug*."

Molina Reviewer Note: Medical necessity review for a psychiatric condition cannot require trial of other medications first. This is applicable to formulary medications that require prior authorization and non-formulary medications and is not limited to only medications designated 'ST'. If the requested drug is a brand name and the generic is on formulary, request can be reviewed for specific medical reason generic cannot be used.

New Mexico (Source: New Mexico)

"Weight Loss Programs: Covered: Dietary evaluations and counseling for the medical management of morbid obesity and obesity. *Prescription drugs medically necessary for the treatment of obesity and morbid obesity are also covered.* See also, benefits described under Bariatric Surgery. Not Covered: The following are not covered: Treatments and medications for the purpose of weight reduction or control, except for medically necessary treatment of morbid obesity and obesity. Exercise equipment, videos, personal trainers, club members and weight reduction programs."

MOLINA REVIEWER NOTE: Phendimetrazine and phentermine are on formulary.

New York Essential Plan (Source: New York State)

Insurance Law §4303(s) "A hospital service corporation or health service corporation which provides coverage for hospital care shall not exclude coverage for hospital care for diagnosis and treatment of *correctable medical conditions* otherwise covered by the policy solely because the medical condition results in infertility; provided, however that:… (C) provided, further however, every such policy which provides coverage for prescription drugs shall include, within such coverage, coverage for prescription drugs approved by the federal Food and Drug Administration for use in the diagnosis and treatment of infertility in accordance with paragraph three of this subsection."

MOLINA REVIEWER NOTE: Clomiphene is on formulary.

Ohio (Source: Ohio Revised Code)

Chapter 1751 Health Insuring Corporation Law Section 1751.01 Health insuring corporation law definitions "As used in this chapter:
(A)(1) "Basic health care services" means the following services when medically necessary:
(a) Physician's services, except when such services are supplemental under division (B) of this section;
(b) Inpatient hospital services;
(c) Outpatient medical services;
(d) Emergency health services;
(e) Urgent care services;
(f) Diagnostic laboratory services and diagnostic and therapeutic radiologic services;
(g) Diagnostic and treatment services, other than prescription drug services, for biologically based mental illnesses;
(h) *Preventive health care services, including, but not limited to, voluntary family planning services, infertility* services, periodic physical examinations, prenatal obstetrical care, and well-child care;
(i) Routine patient care for patients enrolled in an eligible cancer clinical trial pursuant to section 3923.80 of the Revised Code.
"Basic health care services" does not include experimental procedures."
MOLINA REVIEWER NOTE: Clomiphene is on formulary.

Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and
(B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

State Medicaid
New York (Source: New York State Department of Health)
"Medicaid Coverage of Limited Infertility Benefit: Effective October 1, 2019, Medicaid fee-for-service (FFS) and Medicaid Managed Care (MMC) benefits will include medically necessary ovulation enhancing drugs and medical services related to prescribing and monitoring the use of such drugs for *individuals 21 through 44 years of age* experiencing infertility. This applies to MMC plans, including mainstream MMC plans, HIV Special Needs Plans (HIV SNPs), and Health and Recovery Plans (HARPs). FFS and MMC infertility benefits include office visits, hysterosalpingograms, pelvic ultrasounds, blood testing, and ovulation enhancing drugs included in the Medicaid formulary. The ovulation enhancing drugs included in the Medicaid formulary *are bromocriptine, clomiphene citrate, letrozole, and tamoxifen*. FFS and MMC *infertility benefits will be limited to coverage for three (3) cycles of treatment per lifetime*. For Medicaid purposes, infertility is a condition characterized by the incapacity to conceive, defined by the failure to establish a clinical pregnancy after 12 months of regular, unprotected sexual intercourse for individuals 21 through 34 years of age, or after six months for individuals 35 through 44 years of age."
MOLINA REVIEWER NOTE: Clomiphene is on formulary.

Appendix 1:
A finger-tip unit (FTU) is the amount of topical cream or ointment that is from the distal skin-crease to the tip of the index finger. As an estimate, one FTU is an approximate amount needed to treat an area of skin twice the size of the flat of an adult's hand.

Additional reference: https://www.pennine-gp-training.co.uk/res/Eczema%20finger%20tip%20units.pdf

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
A prescribing provider on behalf of the member, may make a request to obtain a medication that is not on the health plan's formulary. The plan will review the medical necessity of this request and respond back to the prescribing provider and the member per regulatory and/or accreditation standards.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All FDA labeled contraindications are exclusions to any therapy.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
NA

REFERENCES

1. Long CC, Finlay AY. The finger-tip unit--a new practical measure. Clin Exp Dermatol. 1991 Nov;16 (6):444-7. doi: 10.1111/j.1365-2230.1991.tb01232.x. PMID: 1806320

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required medical Information Continuation of Therapy Appendix	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q4 2024
REVISION- Notable revisions: Diagnosis Required Medical Information Appendix	Q4 2023

REVISION- Notable revisions: Required Medical Information Continuation of Therapy Place of Administration Route of Administration Coding/Billing Information	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file