Original Effective Date: 09/06/2026
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Last P&T Approval/Version: 07/29/2026
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Policy Number: C30845-A

Icotyde (icotrokinra)

PRODUCTS AFFECTED

Icotyde (icotrokinra)

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:
Plaque psoriasis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. This clinical policy will be reviewed along with state and federal requirements, the benefit being administered and formulary preferencing. 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. 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. The Pharmacy and Therapeutics Committee has determined that biosimilars may be preferred.

A. FOR ALL INDICATIONS:
   1. Member is not on concurrent treatment or will not be used in combination with TNF-inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or

Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
AND

2. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B, tuberculosis, etc.), including clinically important localized infections, according to the FDA label
AND
3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Icotyde include: no labeled contraindications. Avoid treatment with Icotyde in patients with any clinically important active infection until the infection resolves or is adequately treated. Avoid use of live vaccines during treatment with Icotyde.]
AND
4. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: 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. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.
MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.

B. MODERATE TO SEVERE PLAQUE PSORIASIS:
1. Documented diagnosis of moderate to severe psoriasis (BSA $\geq$ 3%) OR < 3% body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (e.g., face, neck, hands, feet, genitals)
AND
2. (a) Documentation of treatment failure or serious side effects to TWO of the following systemic therapies for ≥ 3 months: Methotrexate (oral or IM at a minimum dose of 15 mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, or tacrolimus
OR
(b) Documentation of treatment failure to Phototherapy for ≥3 months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation. Provider to submit documentation of duration of treatment, dates of treatment, or number of sessions.
OR
(c) Documentation of contraindication to systemic therapy and phototherapy
NOTE: Contraindications to phototherapy include type 1 or type 2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time.
AND
3. Documentation by prescriber of baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
4. Documentation member weighs at least 40 kg

CONTINUATION OF THERAPY:

A. PLAQUE PSORIASIS:
1. 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
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., serious infection, elevated liver enzymes, etc.)
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
AND

4. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months
MOLINA REVIEWER NOTE: For Texas Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified dermatologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
12 years of age and older

QUANTITY:
200 mg once daily

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Antipsoriatics - Systemic

FDA-APPROVED USES:
Indicated for the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg who are candidates for systemic therapy or phototherapy.

COMPENDIAL APPROVED OFF-LABELED USES:
None

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 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."

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."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Plaque psoriasis is the most common variant of psoriasis. The most rapid advancements addressing plaque psoriasis have been in its pathogenesis, genetics, comorbidities, and biologic treatments. Plaque psoriasis is associated with a number of comorbidities including psoriatic arthritis, cardiometabolic diseases, and depression. For patients with mild psoriasis, topical agents remain the mainstay of treatment, and they include topical corticosteroids, vitamin D analogues, calcineurin inhibitors, and keratolytics. The American Academy of Dermatology-National Psoriasis Foundation guidelines recommend biologics as an option for first-line treatment of moderate to severe plaque psoriasis because of their efficacy in treating it and acceptable safety profiles. Specifically, inhibitors to tumor necrosis factor α (TNF-α) include etanercept, adalimumab, certolizumab, and infliximab. Other biologics inhibit cytokines such as the p40 subunit of the cytokines IL-12 and IL-23 (ustekinumab), IL-17 (secukinumab, ixekizumab, bimekizumab, and brodalumab), and the p19 subunit of IL-23 (guselkumab, tildrakizumab, risankizumab, and mirikizumab). Biologics that inhibit TNF-α, p40IL-12/23, and IL-17 are also approved for the treatment of psoriatic arthritis. Oral treatments include traditional agents such as methotrexate, acitretin, cyclosporine, and the advanced small molecule apremilast, which is a phosphodiesterase 4 inhibitor. The most commonly prescribed light therapy used to treat plaque psoriasis is narrowband UV-B phototherapy.

Icotyde (icotrokinra) is a peptide that selectively binds to the IL-23 receptor (IL-23R) with a dissociation constant of 7 pM and antagonizes the binding of IL-23. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Icotrokinra inhibits the IL-23/IL-23R-dependent release of proinflammatory cytokines.

The safety and efficacy of Icotyde was evaluated in pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe plaque psoriasis in two placebo-controlled trials (Trial PSO-3 and Trial PSO-4). A total of 72 pediatric subjects were treated with Icotyde 200 mg orally once daily.

Icotyde met all primary efficacy endpoints and demonstrated a favorable safety profile across four Phase 3 studies including 2,500 patients. The approval is based on an unprecedented body of evidence from the ICONIC clinical development program, which simultaneously evaluated Icotyde in adults and adolescents, high impact sites such as scalp and genital PsO, and in duplicate head-to-head trials versus an active comparator. In the head-to-head superiority studies, approximately 70% of patients achieved clear or almost clear skin (IGA0/1) and 55% of patients achieved a Psoriasis Area and Severity Index (PASI) 90 response at Week 16. Rates of adverse reactions for Icotyde treated patients were within 1.1% of placebo through Week 16 and no new safety signals were identified through Week 52.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Icotyde (icotrokinra) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Icotyde include: no labeled contraindications. Avoid treatment with Icotyde in patients with any clinically important active infection (including tuberculosis [TB]) until the infection resolves or is adequately treated. Avoid use of live vaccines during treatment with Icotyde.

Exclusions/Discontinuation:
If a patient develops a clinically important active infection and/or is not responding to standard therapy, monitor the patient closely and discontinue Icotyde until the infection resolves.

OTHER SPECIAL CONSIDERATIONS:
Administer Icotyde (icotrokinra) on an empty stomach with water upon waking. Wait at least 30 minutes after taking Icotyde before eating food. For patients who have difficulty swallowing tablets, Icotyde can be dispersed in water.

Consider evaluating for tuberculosis (TB) prior to initiating treatment with Icotyde based on clinical judgment. Monitor patients for signs and symptoms of active TB during and after treatment with Icotyde.

Monitor for potential adverse reactions when Icotyde is used in patients with eGFR <60 mL/min.

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:
Icotyde TABS 200MG

REFERENCES

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10. ClinicalTrials.gov. (2026). A study of icotrokinra in participants with moderately-to-severely active Crohn's disease (ICONIC-CD) (NCT07196722). Retrieved June 2026, from https://clinicaltrials.gov/study/NCT07196722

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q3 2026