| Effective Date: 11/1/2026 |
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| Reviewed: 8/2026<br>Scope: Medicaid |

# ICOTYDE (icotrokinra)

## POLICY

### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderate to severe plaque psoriasis (PsO) in adults who are candidates for systemic therapy or phototherapy
2. Moderate to severe plaque psoriasis (PsO) in pediatric patients 12 years of age and older who weigh at least 40kg and are candidates for systemic therapy or phototherapy

All other indications are considered experimental/investigational and are not a covered benefit.

### II. CRITERIA FOR INTIAL APPROVAL

**For all indications:**

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Icotyde will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab (e.g., Hadlima), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, Otulfi, Selarsdi, Steqeyma and Yesintek, etc.), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.); AND
- Member is free of any clinically important active infection, including clinically important localized infections; AND
- Member will not receive live vaccines during therapy; AND
- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment.

**A. Moderate to severe plaque psoriasis (PsO)**

Authorization of 6 months may be granted for treatment of moderate to severe plaque psoriasis when all of the following criteria are met:

1. Member is 12 years of age or older; AND
2. Documentation has been submitted that member's weight is at least 40kg; AND
3. Icotyde is prescribed by, or in consultation with, a dermatologist; AND
4. Documentation has been submitted of one or more of the following:
   a. BSA affected is at least 10%; OR
   b. Crucial body areas affected (e.g., face, hands, feet, genitals, scalp); OR
   c. Inadequate treatment response to topical therapy (corticosteroids, calcineurin inhibitors (e.g., tacrolimus), vitamin D analogs (e.g., calcipotriene), retinoids (e.g., tazarotene)); AND
5. Documentation has been submitted that the member meets any of the following criteria:

a. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of a conventional oral agent for PsO (e.g., methotrexate, cyclosporine, or acitretin); OR
b. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of phototherapy (e.g., UVB, PUVA); OR
c. Clinical rationale has been provided indicating member's disease severity warrants a biologic DMARD as first-line therapy; AND

6. Documentation has been submitted that the member meets all of the following:
   a. Member meets either of the following criteria:
      i. If member is 18 years of age or older, member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab AND a 6-month trial of ustekinumab biosimilar at maximum tolerated doses; OR
      ii. If member is under 18 years of age, documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses; AND
   b. Member has also had an inadequate response, intolerance, or contraindication to at least a 6-month trial of one of the following: Cosentyx (secukinumab), Ilumya (tildrakizumab), Tremfya (guselkumab), or Otezla (apremilast).

## III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for all members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and documentation is submitted indicating a positive clinical response as evidenced by low disease activity (e.g., reduction in BSA affected from baseline) or improvement in signs and symptoms of the condition from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)).

## IV. QUANTITY LIMIT

1. Icotyde 200mg tablet – 1 tablet per day

## V. REFERENCES

1. Icotyde [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2026.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019;80(4):1029-1072.
3. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020;82(6):1445-1486.