

icotrokinra (Icotyde™)**Policy # 00983**

Original Effective Date: 08/01/2026

Current Effective Date: 08/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of icotrokinra (Icotyde™)[†] for the treatment of adult patients with plaque psoriasis to be **eligible for coverage**.^{**}

Patient Selection Criteria

Coverage eligibility for icotrokinra (Icotyde) will be considered when the following criteria are met:

Initial

- Patient has a diagnosis of moderate to severe plaque psoriasis; AND
- Patient is greater than or equal to 12 years of age; AND
- Patient weighs at least 40 kg; AND
- Patient has greater than 10% of body surface area (BSA) OR less than or equal to 10% of BSA with plaque psoriasis involving sensitive areas OR areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient is a candidate for phototherapy or systemic therapy; AND
- Patient has failed to respond to an adequate trial of one of the following treatment modalities:
 - Ultraviolet B; OR
 - Psoralen positive Ultraviolet A; OR
 - Systemic therapy (e.g., methotrexate, cyclosporine, acitretin); AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Icotyde is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira[®], biosimilars)[‡] or etanercept (Enbrel[®])[‡] OR other drugs such as tofacitinib (Xeljanz[®]/XR)[‡], or apmilast (Otezla[®]/XR)[‡].
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

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Continuation

- Patient has received an initial authorization for Icotyde; AND
- Patient has experienced a beneficial clinical response from baseline (prior to therapy with Icotyde) as evidenced by improvement in clinical signs and symptoms such as reduced estimated body surface area affected by psoriasis, decreased erythema, induration/thickness, or scaling, and/or improvement in symptoms such as pain, itching, or burning; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Icotyde will NOT be used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla/XR).
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of icotrokinra (Icotyde) when any of the following criteria are not met to be **not medically necessary**.**

- Patient has greater than 10% of body surface area (BSA) OR less than or equal to 10% of BSA with plaque psoriasis involving sensitive areas OR areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia)
- Patient has failed to respond to an adequate trial of one of the following treatment modalities:
 - Ultraviolet B; OR
 - Psoralen positive Ultraviolet A; OR
 - Systemic therapy (e.g., methotrexate, cyclosporine, acitretin)
- Icotyde is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla/XR)
- For continuation requests: Patient has experienced a beneficial clinical response from baseline (prior to therapy with Icotyde) as evidenced by improvement in clinical signs and symptoms such as reduced estimated body surface area affected by psoriasis, decreased erythema, induration/thickness, or scaling, and/or improvement in symptoms such as pain, itching, or burning
- For continuation requests: Icotyde will NOT be used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla/XR).

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of icotrokinra (Icotyde) when patient selection criteria are not met (except those denoted above as **not medically necessary****) to be **investigational**.*

Background/Overview

Icotyde is an interleukin-23 (IL-23) receptor antagonist 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 and are candidates for systemic therapy or phototherapy. The drug works by selectively blocking the IL-23 receptor, a pathway involved in inflammatory signaling in plaque psoriasis. Icotyde is available in 200 mg tablets and is dosed as 200 mg orally once daily. It should be taken upon waking on an empty stomach with water, and patients should wait at least 30 minutes before eating food.

Plaque Psoriasis

Psoriasis is a common, chronic, immune-mediated disease affecting approximately 3% of the U.S. population and an estimated 125 million people worldwide. Plaque psoriasis is the most common form and accounts for more than 80% of cases. It typically presents as raised, erythematous, scaly plaques that vary in size and thickness and most often involve the elbows, knees, scalp, and lower back; however, plaques may also occur in sensitive or functionally important areas such as skin folds, the face, genitals, palms, and soles. Patients with moderate to severe disease or disease exacerbations may experience significant pruritus and quality-of-life impairment.

The etiology of psoriasis is complex and not fully established. The pathogenesis is thought to involve abnormal keratin formation, epidermal proliferation, immune system activation, and hereditary factors. Known triggers include stress, skin injury, certain medications, and infection, particularly streptococcal infection.

Disease severity is generally classified based on lesion location, body surface area involvement, and impact on quality of life. Mild disease is commonly defined as involvement of less than 3% to 5% of body surface area, moderate disease as approximately 3% to 10% or 5% to 10%, and severe disease as 10% or greater. Emollients are recommended for all patients to decrease itching and desquamation. Mild to moderate disease is generally managed with topical therapy, while systemic therapy is a mainstay for moderate to severe disease and may also be used for localized disease involving difficult-to-treat or high-impact areas such as the scalp, palms, soles, or genitals, or for disease that does not adequately respond to topical therapy.

Moderate to severe psoriasis may be complicated by comorbid conditions, including hypertension, obesity, type 2 diabetes, dyslipidemia, metabolic syndrome, and cardiovascular disease. Other conditions, such as chronic obstructive pulmonary disease, asthma, chronic kidney disease, hepatobiliary cancer, and inflammatory bowel disease, may also occur more frequently in patients with psoriasis than in the general population.

Current treatment options for plaque psoriasis include traditional systemic agents such as methotrexate, cyclosporine, and acitretin; phototherapy; targeted oral therapies such as apremilast and deucravacitinib; and biologic therapies targeting tumor necrosis factor, interleukin-17, interleukin-12/23, or interleukin-23 pathways. Joint American Academy of Dermatology and National Psoriasis Foundation guidelines recommend systemic non-biologic and biologic therapies for appropriate patients with moderate to severe plaque psoriasis. Icotyde is not currently addressed in these guidelines.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Icotyde was approved in March 2026 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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Icotyde was evaluated in four multi-center, randomized, double-blind, placebo and/or active comparator-controlled trials (Trial PSO-1, Trial PSO-2, Trial PSO-3, and Trial PSO-4) that included 2500 subjects (2428 adults and 72 pediatric subjects 12 years and older who weigh at least 40 kg) with moderate-to-severe plaque psoriasis who were eligible for systemic therapy or phototherapy.

Adults with Moderate-to-Severe Plaque Psoriasis (Trials PSO-1 and PSO-2)

Trial PSO-1 and Trial PSO-2 enrolled 1505 adults with moderate-to-severe plaque psoriasis defined as Investigator's Global Assessment (IGA) score ≥ 3 , a Psoriasis Area and Severity Index (PASI) score ≥ 12 , and body surface area (BSA) involvement $\geq 10\%$. Subjects were randomized to either Icotyde 200 mg orally once daily, deucravacitinib 6 mg orally once daily or placebo. At Week 16, subjects originally randomized to placebo received Icotyde 200 mg orally once daily thereafter. At Week 24, subjects originally randomized to deucravacitinib received Icotyde 200 mg orally once daily thereafter. Baseline characteristics were consistent across both trials.

Trial PSO-1 and Trial PSO-2 assessed responses at Week 16 for Icotyde compared to placebo for two co-primary endpoints:

- the proportion of subjects who achieved IGA 0/1 response (defined as IGA score of 0 [cleared] or 1 [minimal] with a ≥ 2 -grade improvement from baseline)
- the proportion of subjects who achieved at least a 90% improvement in PASI scores from baseline (PASI 90).

In Trial PSO-1, 68% (213) of patients in the Icotyde group achieved an IGA of 0 or 1 at Week 16 compared to 11% (17) in the placebo group and 50% (154) in the deucravacitinib group. The difference from placebo was 58% (95% CI 50, 64). The PASI 90 results also showed improvement in the Icotyde group vs placebo with 55% in the Icotyde group achieving PASI 90 and 12% in the placebo group. This corresponds to a 51% difference from placebo (95% CI 44, 57).

Trial PSO-2 had similar results with 71% (227) patients in the Icotyde group achieving an IGA of 0 or 1 at Week 16 compared to 9% (7) in the placebo group and 55% (177) in the deucravacitinib group. The difference from placebo was 63% (95% CI 53, 70). The PASI 90 results showed improvement in the Icotyde group vs placebo with 58% in the Icotyde group achieving PASI 90 and 1% in the placebo group. This corresponds to a 57% difference from placebo (95% CI 49, 62).

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Adults and Pediatric Subjects 12 Years of Age and Older with Moderate-to-Severe Plaque Psoriasis (Trial PSO-3)

Trial PSO-3 enrolled 684 subjects (618 adults and 66 pediatric subjects 12 years of age and older who weigh at least 40 kg) with moderate-to-severe plaque psoriasis defined as Investigator's Global Assessment (IGA) score ≥ 3 , a Psoriasis Area and Severity Index (PASI) score ≥ 12 , and BSA $\geq 10\%$. Subjects were randomized to receive either Icotyde (200 mg orally once daily) or placebo for 16 weeks.

Trial PSO-3 assessed responses at Week 16 for Icotyde compared to placebo for two co-primary endpoints:

- the proportion of subjects who achieved IGA 0/1 response (defined as IGA score of 0 [cleared] or 1 [minimal] with a ≥ 2 -grade improvement from baseline)
- the proportion of subjects who achieved PASI 90.

At Week 16, 65% of patients achieved IGA 0/1 response in the Icotyde group and 8% achieved this in the placebo group. This corresponds to a 56% difference from placebo (95% CI 50, 62). The PASI 90 endpoint at Week 16 was met in 50% of those in the Icotyde group and 4% in the placebo group. This corresponds to a 45% difference from placebo (95% CI 40, 50).

Trial PSO-3 included 66 pediatric subjects 12 years of age and older who weigh at least 40 kg. In these patients, 84% achieved an IGA of 0 or 1 in the Icotyde group and 27% achieved this in the placebo group. This corresponds to a 56% difference from placebo (95% CI 33, 74). 70% of pediatric patients in the Icotyde group achieved a PASI 90 at Week 16 compared to 14% of pediatric patients on placebo. This corresponds to a 56% difference from placebo (95% CI 33, 73).

Adults and Pediatric Subjects 12 Years of Age and Older with Moderate-to-Severe Plaque Psoriasis of the Scalp or Genital Area (Trial PSO-4)

Trial PSO-4 enrolled 311 subjects (305 adults and 6 pediatric subjects 12 years of age and older who weigh at least 40 kg) with moderate-to-severe plaque psoriasis who had a minimum BSA involvement of $\geq 1\%$, an IGA score of ≥ 2 and had failed to respond to at least one topical therapy for the treatment of plaque psoriasis. Additionally, subjects in Trial PSO-4 had at least one of the following baseline conditions: ss-IGA score ≥ 3 (at least moderate plaque psoriasis of the scalp), static Physician's Global Assessment of Genitalia (sPGA-G) score ≥ 3 (at least moderate plaque psoriasis of the genital area), and/or Physician's Global Assessment of Hands and/or Feet (hf-PGA) score ≥ 3 (at least moderate plaque psoriasis of the hands and/or feet).

Subjects were randomized to receive either Icotyde 200 mg orally once daily or placebo for 16 weeks. At Week 16, subjects originally randomized to placebo switched to receive Icotyde 200 mg orally once daily, and subjects randomized to Icotyde at baseline remained on treatment through the end of study.

In Trial PSO-4, the primary endpoint was the proportion of subjects who achieved an IGA 0/1 response (defined as IGA score of 0 [cleared] or 1 [minimal] and a ≥ 2 -grade improvement from baseline at Week 16).

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In the Icotyde group, 57% achieved the IGA 0/1 response compared to 6% in the placebo group. This corresponds to a difference for placebo of 51% (95% CI 42, 59). Additionally, 57% in the Icotyde group achieved a PASI 90 response compared to 6% in the placebo group. This corresponds to a difference from placebo of 52% (95% CI 42, 60).

References

1. Icotyde [package insert]. Janssen Biotech, Inc. Horsham, PA. Updated March 2026.
2. Icotyde Drug Evaluation. Express Scripts. Updated March 2026.

Policy History

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07/21/2026 Pre Pharmacy and Therapeutics Committee review

07/22/2026 Pharmacy and Therapeutics Committee approval. New policy.

Next Scheduled Review Date: 07/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.