Clinical Policy: Alopecia Areata Treatments

Reference Number: HNCA.CP.CPA.04
Effective Date: 09.25
Last Review Date: 08.25
Line of Business: Commercial, HIM

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The following JAK inhibitors for the treatment of alopecia areata require prior authorization: Baracitinib (Olumiant®), ritlecitinib (Litfulo™), and deuruxolitinib (Leqselvi™) *

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For Health Insurance Marketplace (HIM),** *Use of these products for the treatment of alopecia areata is a benefit exclusion and will not be authorized because it is considered cosmetic in nature.**

FDA Approved Indication(s)

Olumiant is indicated for the treatment of:

- Adults with severe alopecia areata.
- The treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF blockers.*
  **For coverage information for this indication go to CP.CPA.194.*

Litfulo is indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older.

Leqselvi is indicated for the treatment of adults with severe alopecia areata.

Limitation(s) of use: not recommended for use in combination with other JAK inhibitors including topical forms, biologic immunomodulators (DMARDs), cyclosporine, azathioprine or other potent immunosuppressants.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that the member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Baracitinib (Olumiant), Ritlecitinib (Litfulo), and Deuruxolitinib (Leqselvi) are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Alopecia Areata
   1. Diagnosis of severe alopecia areata, defined as ≥ 50% scalp hair loss.
      (See Appendix A for Alopecia Areata Severity Scale which includes severity modifiers)
   2. Member has a current episode of alopecia areata lasting ≥ 6 months.

3. Prescribed by or in consultation with a dermatologist.
4. Age ≥12 for Litfulo, and ≥18 for Olumiant and Leqselvi.
5. Member has tried at least ONE of the following for alopecia areata (a, b or c):
   a) Conventional systemic therapy; OR
      Note: Examples of conventional systemic therapies include corticosteroids, methotrexate, and cyclosporine. An exception to the requirement for a trial of one conventional systemic agent can be made if the patient has already tried one of the following: Olumiant (baricitinib), Litfulo (ritlecitinib), or Leqselvi (deuruxolitinib).
   b) High- or super-high potency topical corticosteroid.
   c) Topical immunotherapy (e.g., diphenylcyclopropenone (DPCP) or squaric acid dibutyl ester (SADBE)).
6. Member will not be using the requested product in combination with other JAK inhibitors including topical JAK inhibitors, biologic immunomodulators (DMARDs) or potent immunosuppressants (e.g., azathioprine, cyclosporine). (See Section III: Diagnoses/Indications for which coverage is NOT authorized).
7. Dose does not exceed any of the following (a, b or c):
   a. Olumiant: 4 mg per day;
   b. Litfulo: 50 mg per day;
   c. Leqselvi: 16 mg per day.

Approval Duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), use the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

II. Continued Therapy

Member meets all of the following:

1. Currently receiving the medication via Centene benefit, or documentation supports that the member is currently receiving Olumiant, Litfulo, or Leqselvi for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy as evidenced by improvement in the extent and density of hair regrowth compared to baseline.
3. Member will not be using the requested product in combination with other JAK inhibitors including topical JAK inhibitors, biologic immunomodulators (DMARDs) or potent

immunosuppressants (e.g., azathioprine, cyclosporine). (See Section III: Diagnoses/Indications for which coverage is NOT authorized).

4. If the request is for a dose increase, the new dose does not exceed any of the following (a, b or c):
    a. Olumiant: 4 mg per day;
    b. Litfulo: 50 mg per day;
    c. Leqselvi: 16 mg per day.

Approval Duration: 12 months

Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial or evidence of coverage documents.
B. Combination use with biological disease-modifying antirheumatic drugs (DMARDs) or potent immunosuppressants, including but not limited to Janus kinase inhibitors (JAKi) [e.g., Olumiant, Litfulo, Leqselvi] because of the additive immunosuppression, increased risk of malignancies, as well as increased risk of serious infections.

III. Appendices/General Information

Appendix A: Alopecia Areata (AA) Severity Scale*

Severity	**Extent of scalp hair loss**
Mild AA	20% or less scalp hair loss
Moderate AA	21%-49% scalp hair loss
Severe AA	50%-100% scalp hair loss
If mild or moderate, increase AA severity rating by one level if one or more of the following is present: • Negative impact on psychosocial functioning resulting from AA • Noticeable involvement of eyebrows or eyelashes • Inadequate response after at least six months of treatment • Diffuse (multifocal) positive hair pull test consistent with rapidly progressive AA	

*Refer to reference 5 below.

IV. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Baracitinib (Olumiant)	2-4 mg PO QD	4 mg/day
Ritlecitinib (Litfulo)	50 mg PO QD	50 mg/day
Deuruxolitinib (Leqselvi)	8 mg PO QD	16 mg/day

Product Availability

Drug Name	Availability
Baracitinib (Olumiant)	Tablets: 1 mg, 2 mg, 4 mg
Ritlecitinib (Litfulo)	Capsule: 50 mg
Deuruxolitinib (Leqselvi)	Tablet: 8 mg

V. References:

1. Olumiant Prescribing Information. Indianapolis, IN: Eli Lilly and Company; June 2022. Available at: https://olumiant.lilly.com/. Accessed July 30, 2025.
2. Litfulo Prescribing Information. New York, NY: Pfizer Labs, June 2023. Available at: https://www.litfulo.com/, Accessed July 30, 2025.
3. Leqselvi Prescribing Information. Whippany, NJ: Sun Pharmaceutical Industries, July 2024. Available at: https://www.leqselvi.com/. Accessed July 30, 2025.
4. Ludmann, P. Hair Loss Types: Alopecia Areata Diagnosis and Treatment. *American Academy of Dermatology.* August 2024. Available at: https://www.aad.org/public/diseases/hair-loss/types/alopecia/treatment, accessed July 9, 2025.
5. King, Brett A, et.al. Development of the alopecia areata scale for clinical use: Results of an academic–industry collaborative effort. *Journal of the American Academy of Dermatology*, Volume 86 (Issue 2): 359-364. Available at: https://www.jaad.org/article/S0190-9622(21)02387-2/fulltext.
6. Sibbald, C. Alopecia areata: An updated review for 2023. *J Cutan Med Surg*. 2023, Jun 20;27(3):241-259. https://doi.org/10.1177/12034754231168839.
7. Harries, Matthew J, et.al. British association of dermatologists living guideline for managing people with alopecia areata 2024. *British Journal of Dermatology*, Volume 192, Issue 2, February 2025, Pages 190–205, https://doi.org/10.1093/bjd/ljae385.
8. American Academy of Dermatology Association. (n.d.). *Alopecia areata: Diagnosis and treatment*. Retrieved August 5, 2025, from https://www.aad.org/public/diseases/hair-loss/types/alopecia/treatment

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.30.25	09.25
Revised to add HIM line of business to the policy.	11.24.25	11.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of

physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.