Deuruxolitinib (LEQSELVI) in Alopecia Areata
National Drug Mini-Monograph

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VA Pharmacy Benefits Management Services and National Formulary Committee

The purpose of VA PBM Services drug monographs is to provide a focused drug review for making formulary decisions. The Product Information or other resources should be consulted for detailed and most current drug information.

Abbreviations: AA, alopecia areata; AC, active-controlled; aka, also known as; ALC, absolute lymphocyte count; ANC, absolute neutrophil count; CPK, creatine phosphokinase; DILI, drug-induced liver injury; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; Hg, hemogobin; HLD, hyperlipidemia; MC, multicenter; MN, multinational; OLE, open-label extension; PC, placebo-controlled; PLT, platelet(s); Q, GRADE quality of evidence; RCT, randomized clinical trial; URTI, upper respiratory tract infection

FDA APPROVAL INFORMATION	
Description / MOA	Deuruxolitinib is a deuterated Janus kinase inhibitor (JAKi) with selectivity for JAK1, JAK2, and TYK2 enzymes. Aka CTP-543. Deuruxolitinib is the third systemic JAKi approved for the treatment of severe alopecia areata, following approvals of baricitinib, which is relatively selective for JAK1, JAK2, and TYK2, and ritlecitinib, which is relatively selective for JAK3 and the tyrosine kinase expressed in hepatocellular carcinoma (TEC) kinase family.
Indication Under Review[1]	Treatment of adults with severe alopecia areata
Dosage Regimen	8 mg twice daily with or without food *Limitations of Use*: Not recommended in combination with other JAKis, biologic immunomodulators, cyclosporine, or other potent immunosuppressants.
Dosage Form Under Review	8-mg tablets
Storage Considerations	• Deuruxolitinib must be stored and dispensed only in the original bottle to protect from moisture. • Ritlecitinib also must be kept in the original package. • Baricitinib does NOT require dispensing in the original bottle.
Pretreatment Evaluations and Vaccinations	• Determine CYP2C9 genotype. Deuruxolitinib is contraindicated in CYP2C9 poor metabolizers. An FDA-cleared or -approved test for detection of CYP2C9 variants to direct the use of deuruxolitinib is not currently available. • Evaluate for use of concomitant CYP2C9 inhibitors. Deuruxolitinib is contraindicated in patients taking moderate or strong CYP2C9 inhibitors. • Evaluate for active and latent tuberculosis (TB). Deuruxolitinib is not recommended in patients with active TB. Start preventive therapy for TB before initiating deuruxolitinib in patients with latent TB or a negative latent TB test who are at high risk of TB. • Screen for viral hepatitis. Deuruxolitinib is not recommended in active hepatitis B or hepatitis C infection. • If patient has hepatitis B infection, follow treatment guidelines or refer to a liver specialist. Monitor for reactivation during treatment as per clinical guidelines. • Obtain complete blood count (CBC). Deuruxolitinib is not recommended if absolute lymphocyte count (ALC) is < 500 cells/mm^3, absolute neutrophil count (ANC) is < 1,000 cells/mm^3, or hemoglobin is < 8 g/dL. Monitor CBC periodically during therapy and modify dosage as recommended. • Obtain lipid panel. Monitor lipids periodically during therapy. • Complete any necessary immunizations, including herpes zoster vaccinations, as per guidelines.

Treatment Interruption and Resumption	• Serious or opportunistic infections • ALC < 500 cells/mm^3. Resume when count is ≥ 500 cells/mm^3. • ANC < 1000 cells/mm^3. Resume when count is ≥ 1000 cells/mm^3. • Hemoglobin (Hg) < 8 g/dL. Resume when value is ≥ 8 g/dL. • No recommendation for low platelet (PLT) count.

EFFICACY CONSIDERATIONS

Phase 3 Trials

Two phase 3 RCTs were conducted, one of which is published (THRIVE-AA1).[2]

Published Trial

Efficacy and safety of deuruxolitinib, an oral selective Janus kinase inhibitor, in adults with alopecia areata: Results from the Phase 3 randomized, controlled trial (THRIVE-AA1)[3]

Design

24-week multinational, double-blind, placebo-controlled, phase 3 RCT (3:5:2 randomization) with optional open-label extension (OLE) or 4-week posttreatment safety follow-up period.

Randomization was stratified by baseline scalp hair loss (partial or complete, where partial is defined as SALT 50–94 and complete as SALT ≥ 95).

Population

Patients aged 18–65 years with ≥ 50% scalp hair loss (defined as Severity of Alopecia Tool / SALT score ≥ 50) and current episode of alopecia areata (AA) scalp hair loss lasting 6 months to 10 years. Total disease duration > 10 years was allowed.

Exclusions: Recent use of drugs that affect hair regrowth or immune response; history of moderate to severe androgenic alopecia or female pattern hair loss (i.e., hormonally driven AA vs autoimmune).

Median age 37 years; 38% male; 69% White; partial scalp hair loss (SALT ≥ 50 and < 95) 44%; complete or near-complete scalp hair loss (SALT ≥ 95) 56%; median duration of current AA episode 3 years. From US, CN, and EU.

Interventions

Deuruxolitinib 12 mg BID

Deuruxolitinib 8 mg BID

Comparator

Placebo

Results

Week-24 Efficacy Results

Outcome	Deuruxolitinib 12	Deuruxolitinib 8	PBO	Q
SALT ≤ 20, n/N (%)	**83/215 (41.5)**	**94/351 (29.6)**	**1/140 (0.8)**	**L$^{\alpha}$**
RR (95% CI)	54 (7.6, 383.8)	37.5 (5.3, 266.3)	Ref	
ARD (95% CI)	37.9 (31.2, 44.5)	26.1 (21.2, 30.9)	Ref	
SALT ≤ 10, n/N (%)	**74/215 (34.5)**	**73/351 (20.8)**	**0/140 (0.0)**	**L$^{\alpha}$**
RR (95% CI)	Not calculable	Not calculable	Ref	
ARD (95% CI)	34.4 (28.1, 40.8)	20.8 (16.6, 25.0)	Ref	

ARD, absolute risk difference; RR, relative risk:

[α] Downgraded for indirectness (no quality-of-life assessment) and imprecision (wide CI, optimal information size not met)

Patient satisfaction responder rates were 42.1% on 8 mg (N = 351) and 53.0% on 12 mg (N = 215) vs 4.7% on placebo (N = 140). Patient satisfaction was measured with the satisfaction of hair patient-reported outcome (SPRO) question, with SPRO responders defined as 1 / Very Satisfied or 2 / Satisfied on a scale of 1 / Very Satisfied to 5 / Very Dissatisfied.

Authors' Conclusions

Deuruxolitinib therapy significantly increased scalp hair growth as early as 8 weeks and hair growth continued through 24 weeks, with corresponding improvement in patient satisfaction. Deuruxolitinib was well tolerated. Analyses of longer-term efficacy and safety are being conducted.

SAFETY CONSIDERATIONS

CYP2C9 Poor Metabolizers

Modeling studies showed higher exposure to deuruxolitinib in CYP2C9 poor metabolizers, which may increase the risk of serious adverse reactions.

Before initiation of deuruxolitinib, test patients to determine CYP2C9 genotype.

Selected Safety Data from THRIVE-AA1

Adverse Event	Deuruxolitinib 12 mg	Deuruxolitinib 8 mg	PBO
Serious TEAE, n/N (%)	1 (0.5)	4 (1.1)	4 (2.9)
Discontinuation due to AE	6 (2.8)	9 (2.6)	2 (1.4)
Infections	63 (29.3)	83 (23.7)	31 (22.1)
Herpes zoster	1 (0.5)	1 (0.3)	0

There were no reports of death, malignancy, myocardial infarction, stroke, pulmonary embolism, deep vein thrombosis, or gastrointestinal perforation in any treatment group.

Long-term Durability and Safety

No published extension study was found.

Selected Safety Data from FDA Review[2]

Serious Adverse Events	During the two phase 3 trials and OLE, 8 serious adverse thromboembolic events were reported in 5 study patients on deuruxolitinib 12 mg. A regulatory partial clinical hold was placed on this dose because of the increased risk of significant illness or injury.
Dose-related TEAEs	Thrombosis, lymphopenia, leukopenia, anemia, neutropenia, skin and soft tissue infections, herpes, bronchitis, hyperlipidemia, and increased blood CPK occurred at higher rates on deuruxolitinib 12 mg than 8 mg. The increased risk of potentially life-threatening thrombotic events with the 12-mg dose led to the approval of only the 8-mg dose, the contraindication of concomitant CYP2C9 inhibitors, and the requirement for pretreatment CYP2C9 genotyping to exclude CYP2C9 poor metabolizers.

SAFETY PROFILES OF JAK INHIBITORS APPROVED FOR SEVERE ALOPECIA AREATA

Safety Issue	Deuruxolitinib	Baricitinib	Ritlecitinib
Boxed Warnings	Serious infections / TB Mortality, malignancy, MACE, thrombosis	Same (JAKi class safety labeling)	Same (JAKi class safety labeling)
Contraindications	CYP2C9 poor metabolizers Concomitant moderate or strong CYP2C9 inhibitors	None	Known hypersensitivity
Other Warnings / Precautions	Increased risk of serious adverse reactions in CYP2C9 poor metabolizers or with concomitant use of moderate or strong CYP2C9 inhibitors (see contraindications) GI perforations Lab abnormalities: ALC, ANC, Hg, lipids Avoid live vaccines during or immediately prior to deuruxolitinib therapy	Hypersensitivity GI perforations Lab abnormalities: ALC, ANC, Hg, liver enzymes, lipids Avoid with live vaccines	Hypersensitivity Lab abnormalities: ALC, PLT Avoid live vaccines during or shortly prior to ritlecitinib therapy
5 Most Common AEs in AA	Headache, acne, nasopharyngitis, increased blood CPK, HLD	URTIs, headache, acne, HLD, CPK increase	Headache, diarrhea, acne, rash, urticaria

Safety Issue	Deuruxolitinib	Baricitinib	Ritlecitinib
Renal Impairment	Not recommended in severe or end-stage renal disease (eGFR < 30 mL/min). No dosage adjustment needed for mild or moderate renal impairment.	Not recommended if eGFR < 30 mL/min/1.73 m^2. Reduce dose for moderate renal impairment (eGFR is 30 to < 60 mL/min/1.73 m^2): from 2 mg to 1 mg or from 4 mg to 2 mg once daily. No dosage adjustment needed for mild renal impairment.	No dosage adjustment recommendations for renal impairment
Hepatic Impairment Mild = Child Pugh A Moderate = Child Pugh B Severe = Child Pugh C	Not recommended in severe hepatic impairment. No dosage adjustment needed in mild or moderate hepatic impairment.	Not recommended in severe hepatic impairment. No recommendations for dosage adjustment in mild or moderate hepatic impairment.	Same as for deuruxolitinib
Increased Liver Enzymes / DILI	—	Interrupt therapy if ALT / AST increases and DILI is suspected.	Interrupt therapy if ALT / AST increases and DILI is suspected.
Not recommended if ALC	< 500 cells/mm^3	< 500 cells/mm^3	< 500 cells/mm^3
Not recommended if ANC	< 1000/mm^3	< 1000 cells/mm^3	—
Not recommended if Hg	< 8 g/dL	< 8 g/dL	—
Not recommended if PLT Count	—	—	< 100,000/mm^3
Increased Creatine Phosphokinase (CPK)	Reported as adverse reaction. No CPK monitoring recommendation.	Same	Same
Drug Interaction Dosage Adjustments in AA	See contraindications.	Dosage adjustment needed with strong OAT3 inhibitors (e.g., probenecid). See prescribing information for details.	Additional monitoring and dosage adjustment may be needed for CYP3A substrates and CYP1A2 substrates where small concentration changes may lead to serious adverse reactions. Not recommended with strong inducers of CYP3A (e.g., rifampin) – may decrease effects of ritlecitinib

THERAPEUTIC OPTIONS FOR SEVERE ALOPECIA AREATA: PLACE IN THERAPY					
DRUG	**SALT ≤ 10 ARD**	**VANF**	**CFU**	**FDA**	**GUIDELINES**
Deuruxolitinib LEQSELVI	21%–24%, W24	No	TBD	Adults with severe AA	BAD (2024/2025)[4] recommends a JAKi for severe cases.
Baricitinib OLUMIANT	9% (2 mg)–23% (4 mg), W36	No	No prerequisite treatments	Adults with severe AA	
Ritlecitinib LITFULO	11.9%, W24	No	No prerequisite treatments	Adults and adolescents ≥ 12 years of age with severe AA	

Severe alopecia areata can be defined as ≥ 50% hair loss.
ARD, absolute risk difference vs placebo; BAD, British Association of Dermatologists

POTENTIAL PLACE IN THERAPY	
1L Therapy for Severe AA	1. Given the lack of head-to-head comparisons, the place in therapy of deuruxolitinib in the treatment of severe alopecia areata is unclear, and no systemic JAKi for AA has been shown to be better than the others. Deuruxolitinib may be used as first-line (1L) therapy for severe AA like other systemic JAKis approved for this indication. In general, systemic JAK inhibitors provide alternatives to conventional synthetic immunomodulators (cyclosporine, methotrexate, and azathioprine), which have lower-quality evidence to support their use and are associated with different safety concerns. 2. One of the main disadvantages of deuruxolitinib relative to the other JAK inhibitors are the contraindications in CYP2C9 poor metabolizers and moderate or strong CYP2C9 inhibitors, and the need to check pre-treatment CYP2C9 genotype, a lab test that may not be widely available. 3. An issue for consideration is the lack of long-term safety and durability data for deuruxolitinib. Another consideration is that deuruxolitinib has straightforward dosing (the initial and maintenance dosages are the same, 8 mg twice daily), although baricitinib therapy offers the ability to start with a lower, less costly dose, which may be effective for some patients. 4. Use of JAKis for the treatment of severe AA should consider the risk-benefits of using therapy that can result in increased mortality, malignancy, MACE, and thrombosis for a nonfatal but potentially psychologically devastating disease.

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References

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