PATIENT ACCESS SUPPORT KIT

Recommended practices and letter templates for appealing denials of prior authorizations

The information herein is provided for educational purposes and does not constitute legal advice. When completing a prior authorization request or an appeal, it is the responsibility of the healthcare provider to ensure adherence to the payer's requirements. Payers' public and nonpublic requirements may change, and LEO Pharma undertakes no obligation to provide updated information with respect to such requirements. Under no circumstances should any product or ancillary supplies that are received free of charge be billed to any third-party payer. LEO Pharma cannot and will not guarantee coverage, and nothing herein shall be construed to create such a guarantee.

INDICATION

ADBRY® (tralokinumab-ldrm) injection is indicated for the treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. ADBRY can be used with or without topical corticosteroids.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

ADBRY is contraindicated in patients who have known hypersensitivity to tralokinumab-ldrm or any excipients in ADBRY.

Click here for continued Important Safety Information.
Click here for full Prescribing Information.

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Please contact me if you have any questions.

Name	
Title	
Email	
Phone	

ICD-10, *International Classification of Diseases, Tenth Revision;* NDC, National Drug Code.

Click tabs to go to section.

Click here for continued Important Safety Information.
Click here for full Prescribing Information.

Adbry®
(tralokinumab-ldrm)
Injection 150 mg • 300 mg

Not actual size.

With the Adbry® Autoinjector...

The choice is yours

ONE INJECTION

every other week after initial loading dose[1]*

OR

once monthly after 16 weeks[1†]

13 DOSES A YEAR‡

Your patients. Your choice.

- 2 device options for adults[1]
- Flexible dosing option after 16 weeks[1†]

Not actual size.

1. ADBRY. Prescribing Information. LEO Pharma Inc.

*Initial loading dose is two 300-mg injections.[1]

†q4w for adult patients <220 lbs who achieve clear or almost clear skin after 16 weeks.

‡Number of q4w injections for a full year of treatment after Week 16.

The patient must be: (i) twelve (12) years of age and older for the Prefilled Syringe; or (ii) eighteen (18) years of age and older for the Autoinjector or Prefilled Syringe; and (iii) have a valid prescription for an approved use of the Product.

IMPORTANT SAFETY INFORMATION *cont'd*

WARNINGS AND PRECAUTIONS

- **Hypersensitivity:** Hypersensitivity reactions, including anaphylaxis and angioedema have occurred after administration of ADBRY. If a serious hypersensitivity reaction occurs, discontinue ADBRY immediately and initiate appropriate therapy.
- **Conjunctivitis and Keratitis:** Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received ADBRY. Conjunctivitis was the most frequently reported eye disorder. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

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Adbry®
(tralokinumab-ldrm)
Injection 150 mg • 300 mg

Adbry® advocate®

Support for your patients, your way

An option to suit your workflow

1. To minimize delays, submit the Enrollment Form (EF) or the prescription directly to an Adbry® in-network specialty pharmacy (SP)[a]

- Fax the EF or your prescription form to an Adbry in-network SP. A list of these SPs is located **here** and is also available from the Field Reimbursement Manager (FRM)
- Eligible, commercially insured patients have access to the Adbry Copay Program[b,c,d]
- SPs may also refer eligible patients to the Adbry® Advocate® Program for enrollment in the Adbry® Rapid Access™ and Adbry® Bridge Care™ programs if needed[b,c,e]

2. For eligible patients who may require additional support,[b] submit to both an Adbry in-network SP *and* the Adbry Advocate Program, for example, patients:

- Who are not covered by insurance
- Whose initial prior authorization has been denied
- Who may require access to the Adbry Rapid Access and Adbry Bridge Care programs[b,c,e]

In addition to sending your prescription to an in-network SP, fax the EF to the Adbry Advocate Program at **855-423-0011, or enroll online.**
(See details on the next page.)

If requested, the FRM or Case Manager can help track your patient's benefits investigations and prior authorizations if a completed EF with patient consent is provided.

[a] Some PBMs require the use of affiliated SPs.

[b] Patient is not eligible for the Program if enrolled in any federally or state-funded healthcare program, including but not limited to Medicare (including Medicare Part D), Medicaid, VA, DOD, TRICARE, or CHIP.

[c] Additional terms, conditions, and eligibility rules apply. Enrollment in Adbry Advocate is not required to obtain copay support. For all other patient support programs, enrollment in Adbry Advocate is required. Patient or healthcare provider may not seek reimbursement for the benefit received from any party. LEO Pharma reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

[d] Program has an annual cap. Program may not be combined with any third-party rebate, coupon, or offer.

[e] The initial dose of Adbry may be shipped either to your office or to the patient after submission of a completed Enrollment Form and Patient Authorization. A program representative will coordinate shipment to a patient, which may extend delivery time. Patients who have been initiated on therapy with samples are not eligible for Rapid Access Product.

Click here for Full Terms, Conditions, and Eligibility Rules. Restrictions apply.

Click here for continued Important Safety Information.

Click here for full Prescribing Information.

Adbry®
(tralokinumab-ldrm)
Injection 150 mg • 300 mg

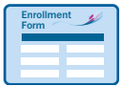
Adbry® advocate®

Support for your patients, your way

If you submit the Enrollment Form (EF) to the Adbry® Advocate® Program, you have options

Fax the EF to: **855-423-0011**

The EF is available at: adbryhcp.com/support-and-resources



Find what you need online

Scan the QR code or go to: adbryhcp.com/support-and-resources

Adbry® advocate®

Your eligible patients can get additional support from the Adbry® Advocate® Program by calling 844-MYADBRY (844-692-3279) between 8 AM–8 PM EST

Or, choose one of the following enrollment options:

Download and complete the Enrollment and Prescription Form and fax to: 855-423-0011

ENGLISH ENROLLMENT FORM

SPANISH ENROLLMENT FORM

Download and fax

Digitally enroll your patients

DIGITAL ENROLLMENT FORM

Submit online

EHR, electronic health record; HCP, healthcare provider.

Click here for continued Important Safety Information.

Click here for full Prescribing Information.

Adbry® (tralokinumab-ldrm) Injection 150 mg • 300 mg

Adbry® advocate®

Support for your patients, your way

Comprehensive patient support programs

Access, Savings, and Support services

- **Adbry® Rapid Access™ Program:** Our goal is for your eligible patients to receive their first dose of Adbry® for free within approximately 48 hours[a,b,c]
- **Adbry® Bridge Care™ Program:** Eligible, commercially insured patients whose insurance does not yet cover Adbry provides for a maximum of six (6) months of shipment of Product, on a periodic basis, within a twenty-four (24) month consecutive time period commencing on the initial date of dispense for such patient's lifetime, or until such patient receives insurance coverage approval, whichever occurs earlier[b,c]
- **Adbry Copay Program:** Eligible, commercially insured patients may pay as little as a $0 copay per fill[b,c,d]
- **Adbry Patient Assistance Program:** Eligible patients with demonstrated financial need and with limited or no prescription coverage may be able to receive Adbry at no cost[c,e]

Case Manager Support

- The Case Manager conducts HCP and patient welcome calls. A Case Manager can also answer any questions about program services as the patient moves through their treatment journey
- The Case Manager will also conduct the benefits investigation so that patients can start therapy as quickly as possible

HCP, healthcare provider.

[a] The initial dose of Adbry may be shipped either to your office or to the patient after submission of a completed Enrollment Form and Patient Authorization. A program representative will coordinate shipment to a patient, which may extend delivery time. Patients who have been initiated on therapy with samples are not eligible for Rapid Access Product.

[b] Patient is not eligible for the Program if enrolled in any federally or state-funded healthcare program, including but not limited to Medicare (including Medicare Part D), Medicaid, VA, DOD, TRICARE, or CHIP.

[c] Additional terms, conditions, and eligibility rules apply. Enrollment in Adbry Advocate is not required to obtain copay support. For all other patient support programs, enrollment in Adbry Advocate is required. Patient or healthcare provider may not seek reimbursement for the benefit received from any party. LEO Pharma reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

[d] Program has an annual cap. Program may not be combined with any third-party rebate, coupon, or offer.

[e] Income eligibility requirements apply. Patient may be required to submit documentation of income and insurance coverage status.

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Adbry®
(tralokinumab-ldrm)
Injection 150 mg • 300 mg

Adbry® advocate®

Flexible options

A range of patient support programs for whichever option you choose

Patient initiation options:	BI + PA	Appeals support	Copay support[a,b,c]	Rapid Access™ Program[a,b,d]	Bridge Care™ Program[a,b]	PAP[b,e]
1. To minimize delays: Submit the EF or prescription directly to an Adbry® in-network SP[e]	●	●[g]	●	—[h]	—[h]	—
2. For eligible patients[a] who may require additional support: Submit to both an in-network SP[f] + the Adbry® Advocate® Program	●	●	●	●	●	●
Submit to an out-of-network SP	—	—	—	—	—	—

Click here for Full Terms, Conditions, and Eligibility Rules. Restrictions apply.

1. To minimize delays, submit the Enrollment Form (EF) or the prescription directly to an Adbry in-network specialty pharmacy (SP)[f]

- Eligible, commercially insured patients have access to the Adbry Copay Program[a,b,c]
- SPs may also refer eligible patients to the Adbry Advocate Program for enrollment in the Adbry Rapid Access and Adbry Bridge Care programs if needed[a,b,d]

2. For eligible patients who may require additional support,[a] submit to both an Adbry in-network SP *and* the Adbry Advocate Program

BI, Benefits Investigation; PA, prior authorization; PAP, Adbry Patient Assistance Program.

[a] Patient is not eligible for the Program if enrolled in any federally or state-funded healthcare program, including but not limited to Medicare (including Medicare Part D), Medicaid, VA, DOD, TRICARE, or CHIP.

[b] Additional terms, conditions, and eligibility rules apply. Enrollment in Adbry Advocate is not required to obtain copay support. For all other patient support programs, enrollment in Adbry Advocate is required. Patient or healthcare provider may not seek reimbursement for the benefit received from any party. LEO Pharma reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

[c] Program has an annual cap. Program may not be combined with any third-party rebate, coupon, or offer.

[d] The initial dose of Adbry may be shipped either to your office or to the patient after submission of a completed Enrollment Form and Patient Authorization. A program representative will coordinate shipment to a patient, which may extend delivery time. Patients who have been initiated on therapy with samples are not eligible for Rapid Access Product.

[e] Income eligibility requirements apply. Patient may be required to submit documentation of income and insurance coverage status.

[f] Some PBMs require the use of affiliated SPs.

[g] Level of appeals support from SPs may vary.

[h] SPs may refer eligible, commercially insured patients to the Adbry Advocate Program for enrollment.

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Examples of formulary restrictions

A product may be listed on formulary and covered by a third-party payer, but may nevertheless be subject to coverage conditions or limitations. Common restrictions may include:

Common clinical criteria
Diagnosis and dosing per label[1-7]
May require prescribing by a specialist[5,7]
May require medical records, an explanation of medical necessity, and a baseline evaluation of severity[1,5,7]

Common step-edit criteria
Trial or intolerance to **1 or more** of the following therapeutic classes[1,3-7]: • Medium-to-high-potency topical steroid • Topical calcineurin inhibitor • Topical PDE4 inhibitor
Some plans may require trials of a specific duration.[3,5]
Some plans may require trial of phototherapy or systemic treatments, such as immunosuppressants.[1,3,5]

Criteria based on information from national and regional plans and PBMs for biologics in this class and are current as of January 2026.

PDE4, phosphodiesterase-4; PBM, Pharmacy Benefit Manager.

References: 1. Adbry (tralokinumab-ldrm): prior authorization form. Aetna. Accessed January 20, 2026. es.aetnabetterhealth.com/content/dam/aetna/medicaid/oklahoma/pdf/Adbry-PA-Form-OK-ua.pdf **2.** Cigna: drug quantity management policy—per days: immunologicals—Adbry (tralokinumab-ldrm subcutaneous injection). Cigna. June 25, 2025. Accessed January 20, 2026. https://static.cigna.com/assets/chcp/pdf/coveragePolicies/cnf/cnf_717_coveragepositioncriteria_immunologicals_adbry_dqm_per_days.pdf **3.** Clinical criteria: Adbry (tralokinumab). Anthem. April 25, 2022. Accessed January 20, 2026. https://files.providernews.anthem.com/1651/ING-CC-0208.pdf **4.** Adbry. BlueCross BlueShield Federal Employee Program. April 1, 2024. Accessed January 20, 2026. https://www.fepblue.org/-/media/PDFs/Medical-Policies/2024/March/Mar-2024-Pharmacy-Policies/Remove---Replace/590053-Adbry-tralokinumabldrm.pdf **5.** Request for prior authorization: tralokinumab-ldrm (Adbry). Molina Healthcare. Accessed January 20, 2026. https://www.molinahealthcare.com/providers/ia/medicaid/resources/-/media/Molina/PublicWebsite/PDF/Providers/ia/IA_Pharmacy_Forms/adbry-pa-form-npi-oct-2022_remediated **6.** UnitedHealthcare pharmacy clinical pharmacy programs: Adbry (tralokinumab-ldrm). UnitedHealthcare. July 1, 2025. Accessed January 20, 2026. https://www.uhcprovider.com/content/dam/provider/docs/public/prior-auth/drugs-pharmacy/commercial/a-g/PA-Med-Nec-Adbry.pdf **7.** Prescription & enrollment form: Adbry (tralokinumab-ldrm). Accredo. Accessed January 20, 2026. https://accredo.com/prescribers/referral_forms/adbry.pdf

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Record formulary criteria for key plans

In the fields below, you can type in key information for plans in your area.

Type in plan name	Date

Criteria:

Type in plan name	Date

Criteria:

Type in plan name	Date

Criteria:

Type in plan name	Date

Criteria:

An FRM may be able to help provide this information.

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Adbry®
(tralokinumab-ldrm)
Injection 150 mg • 300 mg

Recommended practices and sample letter templates

Click to navigate

Recommended practices for prior authorization submissions

Sample Letters:

Letters are available as editable Word documents from the FRM and at adbry.com/downloadable-resources.

Recommended practices for prior authorization submissions

Generally, prior authorization (PA) requests should be submitted using forms provided by the health plan or the specialty pharmacy.

PA forms commonly ask for the following types of information:

Member and provider information

- Patient name, policy number, group number, date of birth, height, and weight
- Provider name, specialty, NPI#, and contact information

Diagnosis

- Diagnosis (click here for a list of potentially applicable ICD-10 codes)
- Drug allergies

Medication information

- Verification that dosing is according to label
- Verification that Adbry® (tralokinumab-ldrm) will not be used in combination with another biologic for the same condition
- History of prior drug therapies: failure, contraindication, or intolerance with dates of use and reason for failure
- Contraindications

Clinical information

- Estimated BSA % affected
- Description of affected sensitive areas, if applicable

Consider making your initial PA request as comprehensive as possible by including:

- Chart notes, along with labs and tests that may support the diagnosis
- Baseline evaluation with the scoring tools, such as EASI, IGA, POEM, or SCORAD
- Description of other features of disease
- Patient's narrative on the condition's impact on the patient's life

NPI, National Provider Identifier; ICD-10, *International Classification of Diseases, Tenth Revision*; BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; POEM, Patient-Oriented Eczema Measure; SCORAD, Scoring Atopic Dermatitis.

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1 Checklist for preparing a

Prior Authorization Appeal letter

Sometimes, it may be necessary to submit an appeal. Keep in mind that the individual reviewing the appeal letter may not be the same person who denied the prior authorization request, so it's important to include comprehensive information in the appeal even if it was included with the initial PA. Submit on your letterhead. Some plans will require that appeals be submitted using their own form.[a]

Core information

- Restate the reason for the denial, which must be provided to you if a prior authorization request is denied
- Describe your clinical rationale for prescribing Adbry® (tralokinumab-ldrm)
- Explanation of why the preferred formulary option or trials with other therapies are not appropriate for your patient

Diagnosis

- Include the patient's diagnosis and appropriate diagnosis code

Clinical information

- Patient history, including chart notes
- Body surface area (BSA) affected; description of affected sensitive areas, especially when BSA is <10%
- Consider including a baseline evaluation with a scoring tool, such as EASI, IGA, POEM, or SCORAD
- Consider including a **body diagram** or photos, if available, prior to start of therapy
- Skin features, presence of infection
- Relevant comorbidities

Medical information

- History of prior therapies: failure or intolerance, with dates of use
- Contraindications
- Verification that Adbry will not be used in combination with another biologic for the same condition

Patient narrative describing the impact of the condition

Consider including a Letter of Medical Necessity (click **here**)

Adbry Prescribing Information

[a] It is always the responsibility of the healthcare provider or other person or entity completing the prior authorization appeal to consult directly with each individual payer to ensure adherence to that payer's requirements.

EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; POEM, Patient-Oriented Eczema Measure; SCORAD, Scoring Atopic Dermatitis.

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Injection 150 mg • 300 mg

1 Sample

Prior Authorization Appeal letter

[Date]
[Medical Director]
[Health Plan or PBM]
[Address]

[Patient Name]
[Member Number, Group Number]
[DOB]
[Denial Reference # and Date of Denial]

To whom it may concern:

My name is [HCP name], [board-certified in specialty, NPI#]. I am writing to request reconsideration of the prior authorization denial for the treatment of [patient name] with Adbry® (tralokinumab-ldrm) for [diagnosis and ICD-10 code]. This patient has been under my care since [date].

The reason given for the denial was [insert reason from the denial letter]. I have reviewed the denial letter and maintain that Adbry is the appropriate treatment at this time because [insert your rationale]. Additional information concerning the patient is reflected below and in the accompanying documentation.

[If this is an appeal of a 2nd or 3rd denial, include a copy of the letter, restate the reason for the denial, and describe why you maintain that Adbry is the appropriate treatment.]

Patient's symptoms

- Affected body surface area (BSA) ( ) ≥10% ( ) less than 10% (describe sensitive areas below)
  ( ) face and neck ( ) hands ( ) feet ( ) genitals/groin ( ) scalp
  ( ) intertriginous areas ( ) flexural areas ( ) other: _____
  (Consider including a **body diagram**)
- [Consider including a baseline evaluation with a scoring tool, such as EASI, IGA, POEM, or SCORAD]
- [Describe skin features, such as redness, thickness, excoriation, or lichenification]
- [Include other relevant clinical information]

[Medical history, allergies, and comorbidities]

Treatment history (Include start and stop dates, duration, and response to applicable therapies.)

[List topical calcineurin inhibitors]	[Start date]	[End date]	[Response]
[List topical corticosteroids[a]]	[Start date]	[End date]	[Response]
[Topical PDE4 inhibitor]	[Start date]	[End date]	[Response]
[List oral and topical JAK inhibitors]	[Start date]	[End date]	[Response]
[List systemic immunosuppressants]	[Start date]	[End date]	[Response]
[Phototherapy]	[Start date]	[End date]	[Response]
[Biologic]	[Start date]	[End date]	[Response]

[a] Medium to very high potency.

Contraindications or therapies not well tolerated: [insert therapies]

Taken together, the patient's symptoms and history support the use of Adbry as appropriate and medically necessary. I look forward to your prompt consideration of this appeal. To discuss further, please contact me at [phone #] for a peer-to-peer review.

Sincerely,

Click to open Word version of this letter.

_____

[Healthcare provider's name, signature, and contact information]

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PBM, Pharmacy Benefit Manager; DOB, date of birth; HCP, healthcare provider; NPI, National Provider Identifier; ICD-10, *International Classification of Diseases,Tenth Revision*; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; POEM, Patient-Oriented Eczema Measure; SCORAD, Scoring Atopic Dermatitis; PDE4, phosphodiesterase-4; JAK, Janus kinase.

2 Checklist for preparing a

Medical Exception letter

For commercial plans, you can use a medical exception letter when a drug is not included on formulary, if a formulary decision has not yet been made, or if a drug is subject to an NDC block. Some plans may provide forms on their websites for medical exception letters. For Medicare Part D plans, a Drug Coverage Determination letter is available here.

The letter should be signed by you and your patient.

Core information

- Your rationale for prescribing Adbry® (tralokinumab-ldrm)
- Explanation of why the formulary option or trials with other therapies are not appropriate

Clinical information

- Patient diagnosis (ICD-10 code)
- Patient history, including chart notes
- Body surface area (BSA) affected
- Description of affected sensitive areas, especially when BSA is <10%
- Consider including a baseline evaluation with a scoring tool, such as EASI, IGA, POEM, or SCORAD
- Consider including a **body diagram** or photos, if available, prior to start of therapy
- Skin features, presence of infection
- Relevant comorbidities

Medical information

- History of past treatments: failure or intolerance, with dates of use
- Contraindications
- Verification that Adbry will not be used in combination with another biologic for the same condition

Patient narrative describing the impact of the condition

Adbry Prescribing Information, supporting literature

If this is an appeal of a previous denial, include:

- A copy of the denial letter
- An explanation for your appeal

NDC, National Drug Code; ICD-10, *International Classification of Diseases, Tenth Revision;* EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; POEM, Patient-Oriented Eczema Measure; SCORAD, Scoring Atopic Dermatitis.

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Injection 150 mg • 300 mg

2 Sample

Medical Exception letter

[Date]
[Medical Director]
[Health Plan or PBM]
[Address]

[Patient Name]
[Member Number, Group Number]
[DOB]
[Denial Reference # and Date of Denial]

To whom it may concern:

My name is [HCP name], [board-certified in specialty, NPI#]. I am writing to request a medical exception to cover Adbry® (tralokinumab-ldrm) for the treatment of [diagnosis and ICD-10 code]. [Patient name] has been under my care since [date].

Rationale for coverage [Describe rationale for coverage of Adbry.]

[If this is an appeal of a denial, include a copy of the letter, restate the reason for the denial, and describe why you maintain that Adbry is the appropriate treatment.]

Patient's symptoms

- Severity: Body surface area (BSA) ( ) ≥10% ( ) less than 10% (describe sensitive areas below)
  ( ) face and neck ( ) hands ( ) feet ( ) genitals/groin ( ) scalp
  ( ) intertriginous areas ( ) flexural areas ( ) other: _____
  (Consider including a **body diagram**)
- [Consider including a baseline evaluation with a scoring tool, such as EASI, IGA, POEM, or SCORAD]
- [Describe skin features, such as redness, thickness, excoriation, or lichenification]
- [Include other relevant clinical information]

Treatment history

(Include previous treatments with start and stop dates, duration, and response to therapy.)

Contraindications or therapies not well tolerated: [insert therapies]

Chart notes with relevant clinical history [I have included chart notes supporting my recommendation.]

Taken together, the patient's symptoms and history support the use of Adbry as appropriate and medically necessary. I look forward to your prompt consideration of this request for coverage of Adbry. To discuss further, please contact me at [phone #] for a peer-to-peer review.

Sincerely,

_____
[Healthcare provider's name, signature, and contact information]

_____
Patient's signature

Enc: Adbry Prescribing Information
Letter of Medical Necessity
Patient Letter

Click to open Word version of this letter.

Click here for continued Important Safety Information.
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PBM, Pharmacy Benefit Manager; DOB, date of birth; HCP, healthcare provider; NPI, National Provider Identifier; ICD-10, *International Classification of Diseases, Tenth Revision*; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; POEM, Patient-Oriented Eczema Measure; SCORAD, Scoring Atopic Dermatitis.

3 Checklist for preparing a

Letter of Medical Necessity

The following checklist and letter provide suggestions for the type of information to consider when a letter of medical necessity is appropriate. Consider including a statement of medical necessity along with other types of letters and appeals.

Core information

- Your rationale for prescribing Adbry® (tralokinumab-ldrm)
- Explanation of why the formulary option or trials with other therapies are not appropriate

Clinical information

- Patient diagnosis (ICD-10 code)
- Patient history, including chart notes
- Body surface area (BSA) affected
- Description of affected sensitive areas, especially when BSA is <10%
- Consider including a baseline evaluation with a scoring tool, such as EASI, IGA, POEM, or SCORAD
- Consider including a **body diagram** or photos, if available, prior to start of therapy
- Skin features, presence of infection
- Relevant comorbidities

Treatment information

- History of past treatments: failure or intolerance, with dates of use
- Contraindications
- Verification that Adbry will not be used in combination with another biologic for the same condition

Patient narrative describing the impact of the condition

Adbry Prescribing Information, supporting literature

If this is an appeal of a previous denial, include:

- A copy of the denial letter
- An explanation for your appeal

ICD-10, *International Classification of Diseases, Tenth Revision*; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; POEM, Patient-Oriented Eczema Measure; SCORAD, Scoring Atopic Dermatitis.

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(tralokinumab-ldrm)
Injection 150 mg • 300 mg

Letter of Medical Necessity

[Date]
[Medical Director]
[Health Plan or PBM]
[Address]

[Patient Name]
[Member Number, Group Number]
[DOB]

To whom it may concern:

My name is [HCP name], [board-certified in specialty, NPI#]. I am writing to support the coverage for Adbry® (tralokinumab-ldrm) for the treatment of [diagnosis and ICD-10 code]. [Patient name] has been under my care since [date].

Rationale for coverage

I have read your policy for the formulary management of agents in this category, and in this letter, I explain why, in my clinical judgment, Adbry [dose, frequency] is the appropriate therapy for this patient. [Describe your rationale.]

Patient's symptoms

- Affected body surface area (BSA) ( ) ≥10% ( ) less than 10% (describe sensitive areas below)
  ( ) face and neck ( ) hands ( ) feet ( ) genitals/groin ( ) scalp
  ( ) intertriginous areas ( ) flexural areas ( ) other: _____
  (Consider including a **body diagram**)
- [Consider including another measure of severity, such as EASI, IGA, POEM, or SCORAD]
- [Describe skin features, such as redness, thickness, excoriation, or lichenification]
- [Include other relevant clinical information]

Treatment history

(Include previous treatments with start and stop dates, duration, and response to therapy.)

Contraindications or therapies not well tolerated: [insert therapies]

Chart notes with relevant clinical history

[I have included chart notes supporting my recommendation.]

Taken together, the patient's symptoms and history support the use of Adbry as appropriate and medically necessary. I look forward to your prompt consideration of this request for coverage of Adbry for this patient. To discuss further, please contact me at [phone #] for a peer-to-peer review.

Sincerely,

_____

[Healthcare provider's name, signature, and contact information]

Enc: Adbry Prescribing Information
Medical records

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PBM, Pharmacy Benefit Manager; DOB, date of birth; HCP, healthcare provider; NPI, National Provider Identifier; ICD-10, *International Classification of Diseases, Tenth Revision*; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; POEM, Patient-Oriented Eczema Measure; SCORAD, Scoring Atopic Dermatitis.

Appeal of a Step Therapy Requirement letter

The following checklist and letter provide suggestions for the type of information to consider when coverage has been denied due to a requirement for use of a prior therapy.

Prior to initiating therapy with a biologic such as Adbry® (tralokinumab-ldrm), patients often will have had an inadequate response to topical therapies or will have had contraindications to their use. They may also have had an inadequate response to a biologic. This letter provides a framework for documenting previous treatments, their duration, and patient response.

You can also explain why certain therapies, such as immunosuppressants or systemic corticosteroids, may not be appropriate for your patient and why access to phototherapy may be limited for your patient, or that its scheduling may require time off from work.

Core information

- Restate the reason for the denial, describing the specific therapy or therapies required
- Your rationale for why that step-edit requirement is not appropriate or has been satisfied for your patient
- Also consider therapies the patient received prior to your care or when covered by a different insurer, which could explain why a previous treatment does not appear in their claims data
- Your rationale for prescribing Adbry

Clinical information

- Patient diagnosis (ICD-10 code)
- Patient history, including chart notes
- Body surface area (BSA) affected
- Description of affected sensitive areas, especially when BSA is <10%
- Consider including a baseline evaluation with a scoring tool, such as EASI, IGA, POEM, or SCORAD
- Consider including a **body diagram** or photos, if available, prior to start of therapy
- Skin features, presence of infection

Patient narrative describing the impact of the condition

Adbry Prescribing Information, supporting literature

If this is an appeal of a previous denial, include a copy of the denial letter

ICD-10, *International Classification of Diseases, Tenth Revision;* EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; POEM, Patient-Oriented Eczema Measure; SCORAD, Scoring Atopic Dermatitis.

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Adbry®
(tralokinumab-ldrm)
Injection 150 mg • 300 mg

Appeal of a Step Therapy Requirement letter

[Date]
[Medical Director]
[Health Plan or PBM]
[Address]

[Patient Name]
[Member Number, Group Number]
[DOB]
[Denial Reference # and Date of Denial]

To whom it may concern:

My name is [HCP name], [board-certified in specialty, NPI#]. I am writing to appeal the step therapy requirement which you state in your letter as follows: [copy reason given in the denial letter].

[Patient name] was initially diagnosed with [diagnosis and ICD-10 code] on [date] and has been under my care since [date]. I have outlined my patient's treatment history below, which supports coverage for Adbry® (tralokinumab-ldrm) without the trial of additional therapies. [If appropriate, include care received from other practitioners, during which time the patient may have been covered by another insurer.]

Treatment history (Include start and stop dates, duration, and response to applicable therapies.)

[List topical calcineurin inhibitors]	[Start date]	[End date]	[Response]
[List topical corticosteroids[a]]	[Start date]	[End date]	[Response]
[Topical PDE4 inhibitor]	[Start date]	[End date]	[Response]
[List oral and topical JAK inhibitors]	[Start date]	[End date]	[Response]
[List systemic immunosuppressants]	[Start date]	[End date]	[Response]
[Phototherapy]	[Start date]	[End date]	[Response]
[Biologic]	[Start date]	[End date]	[Response]

[a] Medium to very high potency.

Contraindications or therapies not well tolerated: [insert therapies]

Patient's symptoms

- Body surface area (BSA) ( ) ≥10% ( ) less than 10% (describe sensitive areas below)
  ( ) face and neck ( ) hands ( ) feet ( ) genitals/groin ( ) scalp
  ( ) intertriginous areas ( ) flexural areas ( ) other: _____
  (Consider including a **body diagram**)
- [Consider including a baseline evaluation with a scoring tool, such as EASI, IGA, POEM, or SCORAD]
- [Describe skin features, such as redness, thickness, excoriation, or lichenification]
- [Include other relevant clinical information]

Chart notes with relevant clinical history [I have included chart notes supporting my recommendation.]

Taken together, the patient's symptoms and history support the use of Adbry as appropriate and medically necessary without the trial of additional therapies. I look forward to your prompt consideration of this request for coverage of Adbry for this patient. To discuss further, please contact me at [phone #] for a peer-to-peer review.

Sincerely,

Click to open Word version of this letter.

_____

[Healthcare provider's name, signature, and contact information]

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PBM, Pharmacy Benefit Manager; DOB, date of birth; HCP, healthcare provider; NPI, National Provider Identifier; ICD-10, *International Classification of Diseases, Tenth Revision*; PDE4, phosphodiesterase-4; JAK, Janus kinase; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; POEM, Patient-Oriented Eczema Measure; SCORAD, Scoring Atopic Dermatitis.

5 Checklist for preparing a

Tier Exception letter

When a patient is covered by a government-sponsored healthcare program, such as Medicare or TRICARE, they are not eligible for commercial cost-sharing programs. If your patient cannot afford Adbry® (tralokinumab-ldrm) because it has been placed on a tier with a high copay or coinsurance, you can request that Adbry be placed on a lower tier so that the medication is more affordable. Some plans require the use of their own tiering exception request forms. Check the plan's website.[a,b]

The letter should be signed by you and your patient.

Core information

- Your rationale for prescribing Adbry
- Description of the current plan name, tier, and copay or coinsurance; and why this amount would be a financial burden
- Explanation of why the formulary option or trials with other therapies are not appropriate

Clinical information

- Patient diagnosis (ICD-10 code)
- Patient history, including chart notes
- Body surface area (BSA) affected; description of affected sensitive areas, especially when BSA is <10%
- Consider including a baseline evaluation with a scoring tool, such as EASI, IGA, POEM, or SCORAD
- Consider including a **body diagram** or photos, if available, prior to start of therapy
- Skin features, presence of infection
- Relevant comorbidities

Treatment information

- History of past treatments: failure or intolerance, with dates of use
- Contraindications

Patient narrative describing financial burden of the high copay

If this is an appeal of a previous denial, include a copy of the denial and a response

[a]It is always the responsibility of the healthcare provider or other person or entity completing the appeal to consult directly with each individual payer to ensure adherence to that payer's requirements.

[b]The Medicare Model Determination Request form is available here.

ICD-10, *International Classification of Diseases, Tenth Revision;* EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; POEM, Patient-Oriented Eczema Measure; SCORAD, Scoring Atopic Dermatitis.

Tier Exception letter

[Date]
[Medical Director]
[Health Plan or PBM]
[Address]

[Patient Name]
[Member Number, Group Number]
[DOB]

To whom it may concern:

My name is [HCP name], [board-certified in specialty, NPI#]. I am writing to request a tiering exception for my patient. [Patient name] has been under my care since [date]. I explain below why, in my clinical judgment, Adbry® (tralokinumab-ldrm) [dose, frequency] is the appropriate therapy for this patient and why it's important to make it available with a lower copay. [Describe your rationale.]

[Patient name] is a member of [plan name]. Because Adbry is on [name the tier] with a cost-sharing amount of [enter amount: $XXX.00], it would place a severe financial burden on my patient. I request that you grant an exception and make Adbry available at the cost-sharing amount for the preferred tier.

Here is the patient's relevant clinical information:

Patient's diagnosis: _____ (include ICD-10 code)

Patient's symptoms

- Body surface area (BSA) ( ) ≥10% ( ) less than 10% (describe sensitive areas below)
  ( ) face and neck ( ) hands ( ) feet ( ) genitals/groin ( ) scalp
  ( ) intertriginous areas ( ) flexural areas ( ) other: _____
  (Consider including a body diagram)
- [Consider including another measure of severity, such as EASI, IGA, POEM, or SCORAD]
- [Describe skin features, such as redness, thickness, excoriation, or lichenification]
- [Include other relevant clinical information]

Treatment history

(Include previous treatments with start and stop dates, duration, and response to therapy.)

Contraindications or therapies not well tolerated: [insert therapies]

Chart notes with relevant clinical history

I have also included a letter of medical necessity certifying that I consider this treatment medically necessary.

I look forward to your prompt consideration of this request for a tiering exception, which will help to make this treatment accessible to my patient. To discuss further, please contact me at [phone #] for a peer-to-peer review.

Sincerely,

_____ _____

[Healthcare provider's name, signature, and contact information]

Patient's signature

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Enc: Adbry Prescribing Information
Medical records
Letter of Medical Necessity

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PBM, Pharmacy Benefit Manager; DOB, date of birth; HCP, healthcare provider; NPI, National Provider Identifier; ICD-10, *International Classification of Diseases, Tenth Revision;* EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; POEM, Patient-Oriented Eczema Measure; SCORAD, Scoring Atopic Dermatitis.

Patient narrative

Consider asking patients to prepare a letter to the insurer to support appeals. It should describe the impact of the condition on the patient's life. Patient narratives can accompany any of your appeals.

You can provide the template on the following page or simply copy this list of topic suggestions to help them get started.

Suggestions for writing your own appeal letter

Here are some examples of questions you can think about to help describe the impact of atopic dermatitis on your life. You can include others that are important to you:

- **How long have you had moderate-to-severe atopic dermatitis?**
- **What treatments have you tried to control it prior to requesting coverage for Adbry® (tralokinumab-ldrm)?** List as many as you have tried, with their approximate dates, a description of how well they worked, and any reactions that you had from them.
- **How has atopic dermatitis affected your personal life?**
- **Has it caused you to limit any of your usual activities of daily living?**
- **Has it impacted your ability to work or caused you to miss days of work?**
- **Has the condition had any impact on your ability to sleep?**
- **Has it had an impact on your mental health, such as depression, anxiety, suicidal ideation, and loss of self-esteem?**
- **If you are writing to support a request for lower copay or coinsurance, describe why the current cost-sharing is a financial burden.**

Be sure to include:

- o Your plan name
- o Your member number and your group number
- o Your address and phone number

Click to open Word version of these suggestions.

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Adbry®
(tralokinumab-ldrm)
Injection 150 mg • 300 mg

6 Sample

Patient letter

[Date]
[Medical Director]
[Health Plan or PBM]
[Address]

[Patient Name]
[Member Number]
[Group Number]
[DOB]

To whom it may concern:

My doctor, [enter name of doctor], has recommended Adbry® (tralokinumab-ldrm) for the treatment of [enter name of condition]. I have had this condition [enter approximate duration]. I was initially diagnosed with this condition [enter approximate date of your original diagnosis], and I have been under the care of Dr. [name] since [date].

Treatments that I have used to try and control the condition are:

[List as many as you have tried, with their approximate dates, a description of how well they worked, and any reactions that you had from them.]

- [First treatment]
- [Second treatment]

I would describe the overall impact of the condition on my life this way:

[Describe how it affects your life. For example, you can break up your description into different areas of your life. To help get you started, here are some areas that you can consider including if they are relevant to your experience:

- Your personal life
- Your usual activities of daily living
- Its impact on your ability to work
- Your ability to sleep]

[If you are writing to request a lower copay (called a tiering exception request), describe why the current copay amount is a financial burden.]

I have lived with this condition for [enter how long]. I have tried all the agents that I've listed above, and, as I've described, the condition has affected my life in this way: [summarize the impact].

I would be very grateful if you would cover Adbry as requested by my doctor. My doctor can be reached at [insert doctor's phone number].

Sincerely,

_____

[Your name, signature, and contact information]

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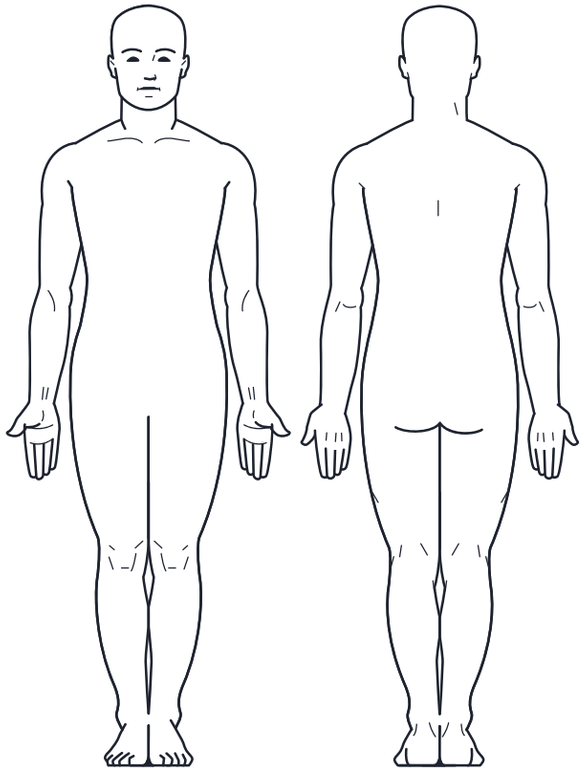
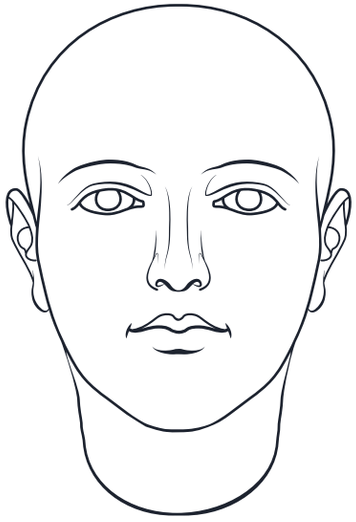
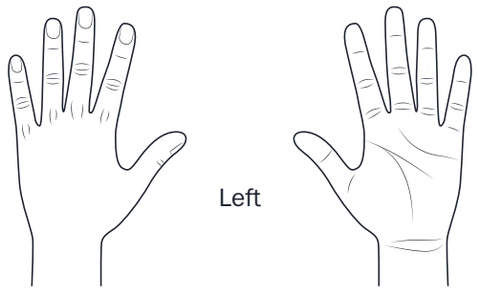
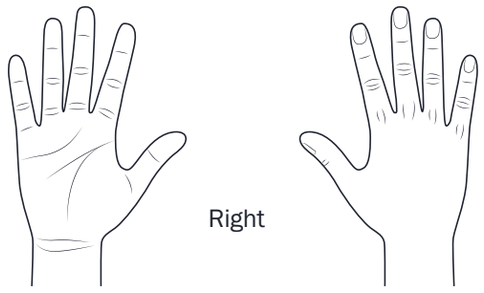
PBM, Pharmacy Benefit Manager; DOB, date of birth.

Body diagrams









I.

ICD-10 codes[1]

Information you submit to healthcare plans must always reflect the appropriate diagnosis codes consistent with the patient's medical records. Potentially applicable diagnosis codes for Adbry® (tralokinumab-ldrm) patient candidates may include the following:

ICD-10 Codes	Descriptors
L20	Atopic dermatitis
L20.0	Besnier's prurigo
L20.81	Atopic neurodermatitis
L20.82	Flexural eczema
L20.84	Intrinsic (allergic) eczema
L20.89	Other atopic dermatitis
L20.9	Atopic dermatitis, unspecified

This information is provided for educational purposes and does not constitute legal advice. This information is believed to be current, but the information may change subsequently, and LEO Pharma disclaims any responsibility to update or revise this information.

NDC information

Prefilled syringes: 150 mg in 1-mL solution	NDC
 Two cartons containing 4 syringes	**10-digit:** 50222-346-04 **11-digit:** 50222034604
One carton containing 2 syringes	**10-digit:** 50222-346-02 **11-digit:** 50222034602
Autoinjectors: 300 mg in 2-mL solution	**NDC**
 One carton containing 2 autoinjectors	**10-digit:** 50222-350-02 **11-digit:** 50222035002
One carton containing 1 autoinjector	**10-digit:** 50222-350-01 **11-digit:** 50222035001

Devices shown are not actual size.

ICD-10, *International Classification of Diseases, Tenth Revision*; NDC, National Drug Code.

1. Atopic dermatitis. ICD10Data.com. Accessed January 20, 2026. https://www.icd10data.com/ICD10CM/Codes/L00-L99/L20-L30/L20-

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Adbry® (tralokinumab-ldrm) Injection 150 mg • 300 mg

INDICATION

ADBRY® (tralokinumab-ldrm) injection is indicated for the treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. ADBRY can be used with or without topical corticosteroids.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

- ADBRY is contraindicated in patients who have known hypersensitivity to tralokinumab-ldrm or any excipients in ADBRY.

WARNINGS AND PRECAUTIONS

- **Hypersensitivity:** Hypersensitivity reactions, including anaphylaxis and angioedema have occurred after administration of ADBRY. If a serious hypersensitivity reaction occurs, discontinue ADBRY immediately and initiate appropriate therapy.
- **Conjunctivitis and Keratitis:** Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received ADBRY. Conjunctivitis was the most frequently reported eye disorder. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.
- **Parasitic (Helminth) Infections:** Treat patients with pre-existing helminth infections before initiating treatment with ADBRY. If patients become infected while receiving ADBRY and do not respond to antihelminth treatment, discontinue treatment with ADBRY until the infection resolves.
- **Risk of Infection with Live Vaccines:** ADBRY may alter a patient's immunity and increase the risk of infection following administration of live vaccines. Prior to initiating therapy with ADBRY, complete all age appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines during treatment with ADBRY. Limited data are available regarding coadministration of ADBRY with non-live vaccines.

ADVERSE REACTIONS

- The most common adverse reactions (incidence ≥1%) are upper respiratory infections, conjunctivitis, injection site reactions, and eosinophilia.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ADBRY during pregnancy. Healthcare providers are encouraged to register pregnant patients, or pregnant women may enroll themselves in the registry by calling 1-877-311-8972 or visiting https://mothertobaby.org/ongoing-study/adbry-tralokinumab/. There are limited data from the use of ADBRY in pregnant women to inform a drug-associated risk of adverse developmental outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, ADBRY may be transmitted from the mother to the developing fetus.
- **Lactation:** There are no data on the presence of tralokinumab-ldrm in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is present in breast milk. The effects of local gastrointestinal exposure and limited systemic exposure to ADBRY on the breastfed infant are unknown.
- **Pediatric Use:** Safety and effectiveness of ADBRY have not been established in pediatric patients younger than 12 years of age

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Adbry® advocate®

Support for your patients, your way

Options for submitting the Enrollment Form (EF) or prescription

1 To minimize delays, submit the EF or the prescription directly to an Adbry® in-network SP[a]

2 For eligible patients who may require additional support,[b] submit to both an Adbry in-network SP ***and*** the Adbry® Advocate® Program

The Enrollment Form is available at:
adbryhcp.com/support-and-resources

Or scan this code:

HCP website: AdbryHCP.com
Consumer website: Adbry.com

Adbry Advocate Program:
Phone: 1-844-MYADBRY (1-844-692-3279)
Hours: 8am–8pm ET
Fax: 855-423-0011
Email: info@adbry-advocate.com

[a] Some PBMs require the use of affiliated SPs.

[b] Patient is not eligible for the Program if enrolled in any federally or state-funded healthcare program, including but not limited to Medicare (including Medicare Part D), Medicaid, VA, DOD, TRICARE, or CHIP.

Please contact me if you have any questions.

Name	
Title	
Email	
Phone	

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June 2026 MAT-94273