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

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 Full Important Safety Information.
Click here for Full Prescribing Information.

Table of Contents

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 Full 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

An option to suit your workflow

1 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 or by eRx.** **(**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 or annual Healthcare Provider eRx Program Certification Form, as applicable, 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.

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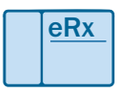
Options for submitting the Enrollment Form (EF) to the Adbry® Advocate™ Program

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

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

Enroll online at Adbryhcp.com/support-and-resources



To ePrescribe Adbry in your EHR:

Submit the **HCP eRx Program Certification Form**. Scan the QR code or fax a copy, available from the FRM, to 855-423-0011. Certification is valid for up to 1 year.

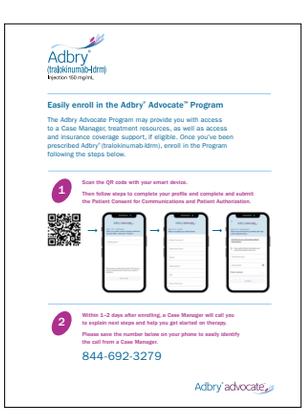
- Select **PharmaCord** in your EHR
  NCPDP: 1836191
  NPI: 1699202838

Include the following:

— Patient name
— Date of birth
— Diagnosis
— Patient's phone number
— Whether patient has received samples

- Direct patient to complete the **Patient Authorization**

The QR code is on the patient information sheet that is available from your FRM or Representative.


Adbry® (tralokinumab-ldrm) Injection 150 mg/mL

Easily enroll in the Adbry® Advocate™ Program

The Adbry Advocate Program may provide you with access to a Case Manager, treatment resources, as well as access and insurance coverage support, if eligible. Once you've been prescribed Adbry® (tralokinumab-ldrm), enroll in the Program following the steps below.

1 Scan the QR code with your smart device.
Then follow steps to complete your profile and complete and submit the Patient Consent for Communications and Patient Authorization.

2 Within 1–2 days after enrolling, a Case Manager will call you to explain next steps and help you get started on therapy.
Please save the number below on your phone to easily identify the call from a Case Manager.
844-692-3279

Adbry® advocate™

HCP, healthcare provider; EHR, electronic health record; NCPDP, National Council for Prescription Drug Programs; NPI, National Provider Identifier.

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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[b,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.

Patient Nursing Support available on request

- The Nurse Advocate can reactively provide education and information about Adbry, and can make medication adherence calls if a patient expresses an interest. Nurse Advocates cannot provide any medical advice and must refer patients to seek the advice of their healthcare provider
- The Nurse Advocate can also arrange for supplemental, virtual patient injection training[c]

Your patients can stay connected with Adbry® Digital Companion

- We've partnered with Medisafe so that patients can stay connected with their support services and access to educational resources

HCP, healthcare provider.

Medisafe is a registered trademark of Medisafe Project LTD.

[a] The initial dose of Adbry may be shipped either to your office or to the patient after submission of a completed Enrollment Form or annual Healthcare Provider eRx Program Certification Form, as applicable, 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® 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]	Virtual supple-mental inj. training[b]	PAP[b,e]	Nursing support on request	Medisafe® app
Option 1: An Adbry® in-network SP[e]	●	●[g]	●	●[h]	●[h]	—	—	—	●
Option 2: An in-network SP[f] + the Adbry® Advocate™ Program	●	●	●	●	●	●	●	●	●
An out-of-network SP	—	—	—	—	—	—	—	—	—

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

[g] Level of appeals support from SPs may vary. [h] SPs may refer eligible, commercially insured patients to the Adbry Advocacy Program for enrollment.

Option 1: 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]

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

SP, specialty pharmacy; PAP, Adbry Patient Assistance Program; BI, Benefits Investigation; PA, Prior Authorization; EHR, electronic health record; NCPDP, National Council for Prescription Drug Programs; NPI, National Provider Identifier; HCP, healthcare provider.

Medisafe is a registered trademark of Medisafe Project LTD.

[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 or annual Healthcare Provider eRx Program Certification Form, as applicable, 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.

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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[a-g]
May require prescribing by a specialist[e,g]
May require medical records, an explanation of medical necessity, and a baseline evaluation of severity[a,e,g]

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

Criteria based on information from national and regional plans and PBMs for biologics in this class and are current as of June 2024.

Click here for references.

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

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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Recommended
practices and sample letter templates

Click to navigate

Recommended practices for Prior Authorization Submissions

Sample Letters:

1 **Prior Authorization Appeal**

2 **Medical Exception**

3 **Medical Necessity**

4 **Appeal of Step Therapy Requirement**

5 **Tier Exception Letter**

6 **Patient Narrative**

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.

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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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, SCORAD, or POEM]
- [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,

_____

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

Double-click to open Word version of this letter.

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PBM, Pharmacy Benefit Manager, DOB, date of birth; HCP, healthcare provider; NPI, National Provider Identifier; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; SCORAD, Scoring Atopic Dermatitis; POEM, Patient-Oriented Eczema Measure; 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, SCORAD, or POEM]
- [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

Double-click to open Word version of this letter.

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

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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3 Sample

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, SCORAD, or POEM]
- [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

Double-click to open Word version of this letter.

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

4 Checklist for preparing an

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; 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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Click here for Full Prescribing Information.

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

4 Sample

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, SCORAD, or POEM]
- [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,

Double-click to open Word version of this letter.

_____

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

Enc: Adbry Prescribing Information, Medical records

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Click here for Full Prescribing Information.

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

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.

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

5 Sample

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, SCORAD, or POEM]
- [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

Double-click to open Word version of this letter.

Enc: Adbry Prescribing Information
Medical records
Letter of Medical Necessity

Click here for Full Important Safety Information.
Click here for Full Prescribing Information.

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

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

Double-click to open Word version of these suggestions.

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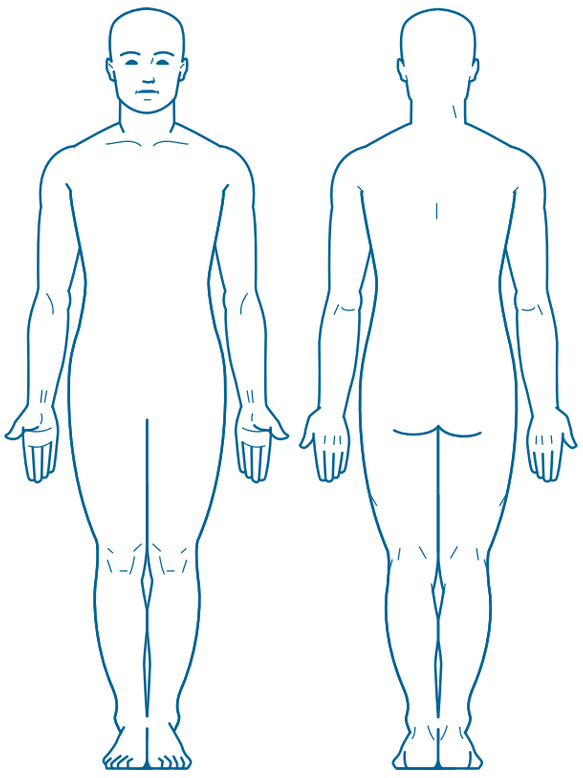
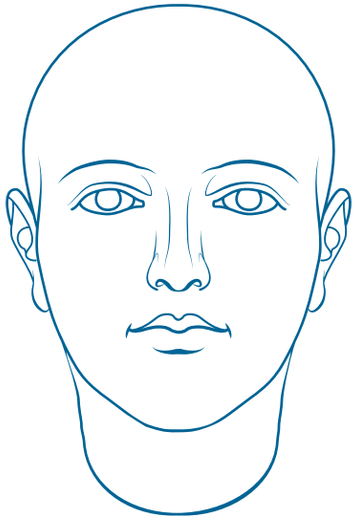
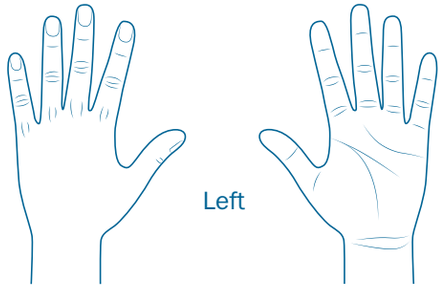
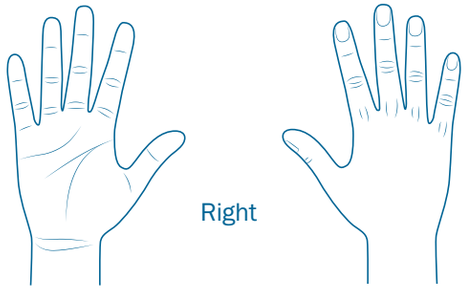
PBM, Pharmacy Benefit Manager; DOB, date of birth.

Body diagrams









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

NDC Number	Strength & UM	Dosage Form	Package Size
10-digit: 50222-346-02 **11-digit:** 50222034602	150 mg/mL	Injection	Pack of 2 syringes
10-digit: 50222-346-04 **11-digit:** 50222034604	150 mg/mL	Injection	2-pack (4 syringes)

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

1. Atopic dermatitis. ICD10Data.com. Accessed June 5, 2024. https://www.icd10data.com/ICD10CM/Codes/L00-L99/L20-L30/L20-

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

ADBRY® ADVOCATE™ PROGRAM FULL TERMS, CONDITIONS, AND ELIGIBILITY RULES

ADBRY® RAPID ACCESS™ PROGRAM – PROGRAM SUMMARY AND TERMS & CONDITIONS

LEO Pharma Inc. ("LEO Pharma") is the distributor of Adbry® (tralokinumab-ldrm) injection (the "Product"). LEO Pharma sponsors the Adbry® Advocate™ patient access programs ("Adbry Advocate") which are operated by LEO Pharma's designated service provider ("LEO Service Provider"). The purpose of Adbry Advocate is to help ensure that medically appropriate patients have access to the medication that has been prescribed for them by their treating healthcare providers (each, an "HCP").

One of the offerings available for the benefit of patients under Adbry Advocate is the Adbry® Rapid Access™ Program (the "Program"). Under the Program, Adbry Advocate will provide the initial (or loading) dose of the Product, consistent with the prescribing information for the Product, without charge, to commercially insured patients who have been prescribed the Product for an approved use and who satisfy the Program eligibility criteria. A patient or their legal representative may enroll in the Program by completing, signing, and submitting the applicable portion of the Adbry Advocate Program Enrollment and Prescription Form. An HCP may prescribe the initial dose of the Product by completing, signing, and submitting the applicable portion of the Enrollment and Prescription Form, which includes a prescription for the Product that will be processed by a non-commercial dispensing pharmacy ("NCDP") affiliated with the LEO Service Provider. Alternatively, a patient's HCP may e-prescribe the Product directly to the NCDP, provided the HCP has completed, signed, and submitted an annual Healthcare Provider eRx Program Certification Form. If the HCP e-prescribes the Product directly to the NCDP, the patient, or their legal representative must complete, sign, and submit a patient authorization and any other information reasonably requested by the Program in order for Adbry Advocate to verify eligibility and for the patient to receive assistance under the Program.

After the prescription is received by the NCDP and the patient's eligibility for the Program is verified, the Product may be delivered to the prescribing HCP's office. Alternatively, if: a) the HCP decides that the patient or caregiver may properly inject the Product; and b) the patient or caregiver received training on the proper preparation and injection of the Product, then the Product may be delivered to the patient's address of record or other location mutually agreed upon by Adbry Advocate and the patient or patient's caregiver. In the event of delivery to the prescribing HCP's office, the Product can usually be delivered in as little as forty-eight (48) hours. In the event of delivery to the patient's address of record or other mutually agreed upon location, Adbry Advocate will coordinate the shipment of the Product, which may extend the delivery time. Product will be dispensed from the NCDP via overnight delivery.

Eligibility Requirements and Limitations

- Patients who have been initiated on therapy with samples are not eligible for Rapid Access Program Product.
- The patient must be 12 years of age or older with a valid prescription for an approved use of the Product.
- The patient must be a resident of the United States or Puerto Rico.
- The patient must have commercial insurance, either directly or through dependent coverage.
- The patient must not have prescription drug coverage for the Product, in whole or in part, either directly or through dependent coverage, under any federal or state health program that is a "federal healthcare program" as defined under 42 U.S.C. § 1320a-7b(f), including but not limited to Medicare, Medicaid, TRICARE, the Indian Health Service, the Department of Veterans Affairs Health Benefit Program, state Children's Health Insurance Programs under the Title XIX or Title XXI of the Social Security Act, state block grant programs under Title V or Title XX of the Social Security Act, or state pharmaceutical assistance programs. This Program is not available for patients within a deductible or similar cost-sharing periods under such federal healthcare programs.
- Uninsured and cash-paying patients are not eligible.

Additional Terms and Conditions

- Good for the initial dose only. Limit of one shipment of Product per eligible patient.
- The Program does not constitute insurance.
- The provision of the initial dose of Product does not constitute any guarantee of coverage under any prescription benefit insurance or program.
- By submitting a request for Product under the Program or by participating in the Program, the HCP acknowledges and agrees that the HCP: (1) will not submit any claim or other request for payment or reimbursement for Product provided under the Program to the patient or any third-party plan or program, including any commercial or government assistance program; (2) will advise the patient that the patient may not submit a claim to any third-party plan or program but should report their receipt of Product to the patient's insurer if required by their plan; (3) will dispense or administer Product solely to the eligible patient for whom such Product was requested; and (4) will not sell, transfer, or otherwise dispense Product to any other third party.
- By submitting a request for Product under the Program or by participating in the Program, the patient (or their legal representative) acknowledges and agrees that the patient: (1) will not submit any claim or other request for payment or reimbursement for Product provided under the Program to any third-party plan or program, including any commercial or government assistance program; (2) will report their receipt of Product to their insurer if required by their plan; and (3) will not sell, transfer, or otherwise dispense Product to any other third party.
- The NCDP only dispenses Product pursuant to the Adbry Advocate patient access programs. Product prescriptions subject to third-party insurance, including refill prescriptions, may be dispensed by the pharmacy of the patient's choice, subject to product distribution and third-party payer limitations.
- Patients and/or their HCPs must submit complete information and/or documentation required under the Program and attest to the truthfulness and accuracy of the information and/or documentation.
- By submitting a request for Product under the Program or by participating in the Program, the patient (or their legal representative) and the HCP individually acknowledge, understand, and agree to the benefit, eligibility, and other program limitations, terms, and conditions as set forth herein.
- The availability of Product under the Program is not conditioned on any past, present, or future purchase, including any potential future refills of Product.
- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") grants individuals rights related to their Protected Health Information ("PHI"). To the extent LEO Pharma receives PHI about you, we will use and disclose it according to the patient authorization that you (or legal representative) have completed for your HCP in connection with the LEO Pharma Adbry Advocate Program. For more information about how your PHI is used and disclosed by your HCP, please review your HCP's Notice of Privacy Practices. To the extent LEO Pharma collects personal data about you that is not PHI, we will use and disclose that personal data as disclosed in our privacy policy, available at Privacy Policy | LEO Pharma (leo-pharma.us). By participating in the LEO Pharma Adbry Advocate Program, you acknowledge that we may collect health information from you, which may be considered "sensitive" data under some U.S. state laws. Moreover, if you are a parent or guardian of a minor participating in the program, you (or legal representative) acknowledge that we may collect data about the participating minor/s, which may also be considered "sensitive" data under some U.S. state laws.
- Offer void where prohibited by law, taxed, or restricted.
- LEO Pharma has sole discretion to determine Program eligibility.
- LEO Pharma may amend, modify, or terminate Program benefits and eligibility criteria at any time and without notice.

Continued

ADBRY® BRIDGE CARE™ PROGRAM – PROGRAM SUMMARY AND TERMS & CONDITIONS

LEO Pharma Inc. ("LEO Pharma") is the distributor of Adbry® (tralokinumab-ldrm) injection (the "Product"). LEO Pharma sponsors the Adbry® Advocate™ patient access programs ("Adbry Advocate") which are operated by LEO Pharma's designated service provider ("LEO Service Provider"). The purpose of Adbry Advocate is to help ensure that medically appropriate patients have access to the medication that has been prescribed for them by their treating healthcare provider ("HCP").

One of the offerings available for the benefit of patients under Adbry Advocate is the Adbry® Bridge Care™ Program (the "Program"). Under the Program, Adbry Advocate will provide the Product, consistent with its prescribing information, without charge and on a periodic basis, to commercially insured patients who have been prescribed the Product for an approved use and who satisfy the Program's eligibility criteria, after experiencing an "Initial Delay" (defined below) in securing a determination of insurance coverage for the Product. A patient or their legal representative may enroll in the Program by completing, signing, and submitting the applicable portion of the Adbry Advocate Program Enrollment and Prescription Form. An HCP may prescribe the Product by completing, signing, and submitting the applicable portion of the Enrollment and Prescription Form which includes a prescription for the Product that will be processed by a non-commercial dispensing pharmacy ("NCDP") affiliated with the LEO Service Provider. Alternatively, a patient's HCP may e-prescribe the Product directly to the NCDP, provided the HCP has completed, signed, and submitted an annual Healthcare Provider eRx Program Certification Form. If the HCP e-prescribes the Product directly to the NCDP, the patient, or their legal representative must complete, sign, and submit a patient authorization and any other information reasonably requested by the Program in order for Adbry Advocate to verify eligibility and for the patient to receive assistance under the Program.

After the prescription is received by the NCDP and the patient's eligibility for the Program is verified, the Product may be delivered to the prescribing HCP's office. Alternatively, if: a) the HCP decides that the patient or caregiver may properly inject the Product; and b) the patient or caregiver received training on the proper preparation and injection of the Product, then the Product may be delivered to the patient's address of record or other location mutually agreed upon by Adbry Advocate and the patient or patient's caregiver. In the event of delivery to the patient's address of record or other mutually agreed upon location, Adbry Advocate will coordinate the shipment of the Product, which may extend the delivery time. Product will be dispensed from the NCDP via overnight delivery.

Eligibility Requirements and Limitations

- The patient must be 12 years of age or older with a valid prescription for an approved use of the Product.
- The patient must be a resident of the United States or Puerto Rico.
- The patient must have commercial insurance, either directly or through dependent coverage.
- The patient must not have prescription drug coverage for the Product, in whole or in part, either directly or through dependent coverage, under any federal or state government subsidized health program that is a "federal healthcare program" as defined under 42 U.S.C. § 1320a-7b(f), including but not limited to Medicare, Medicaid, TRICARE, the Indian Health Service, the Department of Veterans Affairs Health Benefits program, state Children's Health Insurance Programs under the Title XIX or Title XXI of the Social Security Act, state block grant programs under Title V or Title XX of the Social Security Act, or state pharmaceutical assistance programs. This Program is not available for patients within a deductible or similar cost-sharing periods under such federal healthcare programs.
- Uninsured and cash-paying patients are not eligible.
- The patient must experience an "Initial Delay," which is defined as either:
  - A delay of more than seven (7) business days in securing an insurance coverage determination (i.e., the actual submission of a request for coverage determination, such as a prior authorization request), either at therapy initiation or in connection with a change in insurance provider or coverage (i.e., due to a change in employment); or
  - A denial of insurance coverage based on a prior authorization request – either at therapy initiation or in connection with a change in insurance provider or coverage (i.e., due to a change in employment), for which an appeal (or subsequent appeal) of the coverage denial, on behalf of the patient, has been submitted or will be submitted within thirty (30) days of such denial.

Additional Terms and Conditions

- The Program does not constitute insurance.
- The provision of Product under the Program does not constitute any guarantee of coverage under any prescription benefit insurance or program.
- For each eligible patient, the Program provides Product for such patient without charge, 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.
- After eligibility is verified and the prescription is received by the NCDP, the NCDP will ship a supply of Product, in amounts to be determined in the sole discretion of Adbry Advocate, to the prescribing HCP's office, or to the patient, as explained above.
- On a regular basis, Adbry Advocate will verify whether the patient has secured a coverage determination or, if a noncoverage determination has been issued, whether the patient has submitted an appeal. The NCDP will ship additional supplies of Product, in amounts to be determined in the sole discretion of Adbry Advocate, provided the patient remains eligible to receive Product under the Program.
- By submitting a request for Product under the Program or by participating in the Program, the HCP acknowledges and agrees that the HCP: (1) will not submit any claim or other request for payment or reimbursement for Product provided under the Program to the patient or any third-party plan or program, including any commercial or government assistance program; (2) will advise the patient that the patient may not submit a claim to any third-party program or plan but should report their receipt of Product to the patient's insurer if required by their plan; (3) will dispense or administer Product solely to the eligible patient for whom such Product was requested; and (4) will not sell, transfer, or otherwise dispense Product to any other third party.
- By submitting a request for Product under the Program or by participating in the Program, the patient (or their legal representative) acknowledges and agrees that the patient: (1) will not submit any claim or other request for payment or reimbursement for Product provided under the Program to any third-party plan or program, including any commercial or government assistance program; (2) will report their receipt of Product to their insurer if required by their plan; and (3) will not sell, transfer, or otherwise dispense Product to any other third party.
- The NCDP only dispenses Product pursuant to the Adbry Advocate patient access programs. Product prescriptions subject to third-party insurance, including refill prescriptions, may be dispensed by the pharmacy of the patient's choice, subject to product distribution and third-party payer limitations.
- Patients and/or their HCPs must submit complete information and/or documentation required under the Program and attest to the truthfulness and accuracy of the information and/or documentation. Patients may be asked to reverify insurance coverage or appeal status during their participation in the Program. Failure to verify status or to file a required appeal may result in termination of the dispensing of Product under the Program in the sole discretion of Adbry Advocate.
- By submitting a request for Product under the Program or by participating in the Program, the patient (or their legal representative) and the HCP individually acknowledge, understand, and agree to the benefit, eligibility, and other program limitations, terms, and conditions as set forth herein.
- The availability of Product under the Program is not conditioned on any past, present, or future purchase, including any potential future refills of Product.

Continued

ADBRY® BRIDGE CARE™ PROGRAM (CONT'D)

- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") grants individuals rights related to their Protected Health Information ("PHI"). To the extent LEO Pharma receives PHI about you, we will use and disclose it according to the patient authorization that you (or legal representative) have completed for your HCP in connection with the LEO Pharma Adbry Advocate Program. For more information about how your PHI is used and disclosed by your HCP, please review your HCP's Notice of Privacy Practices. To the extent LEO Pharma collects personal data about you that is not PHI, we will use and disclose that personal data as disclosed in our privacy policy, available at Privacy Policy | LEO Pharma (leo-pharma.us). By participating in the LEO Pharma Adbry Advocate Program, you acknowledge that we may collect health information from you, which may be considered "sensitive" data under some U.S. state laws. Moreover, if you are a parent or guardian of a minor participating in the program, you acknowledge that we may collect data about the participating minor/s, which may also be considered "sensitive" data under some U.S. state laws.
- Offer void where prohibited by law, taxed, or restricted.
- LEO Pharma has sole discretion to determine Program eligibility.
- LEO Pharma may unilaterally amend, modify, or terminate Program benefits and eligibility criteria at any time without notice.

ADBRY® COPAY PROGRAM – PROGRAM SUMMARY AND TERMS & CONDITIONS

LEO Pharma Inc. ("LEO Pharma") is the distributor of Adbry® (tralokinumab-ldrm) injection (the "Product"). LEO Pharma sponsors the Adbry® Advocate™ patient access programs ("Adbry Advocate"), which are operated by LEO Pharma's designated service provider. The purpose of Adbry Advocate is to help ensure that medically appropriate patients have access to the medication that has been prescribed for them by their treating healthcare provider ("HCP").

The Adbry® Copay Program (the "Program") will provide reimbursement for eligible, commercially insured patients' cost-sharing obligations (including deductibles, copayments, coinsurance, or amounts in excess of out-of-pocket maximums) for the Product, up to an annual maximum limitation specified by the Program and as may be adjusted from time to time in the Program's sole discretion. The amount of reimbursement may vary, including based on an eligible patient's insurance coverage. Patients may pay as little as $0 per fill of the Product after application of Program reimbursement. Patients remain responsible for any remaining costs for the Product after application of Program reimbursement or reaching the annual maximum limitation.

A patient or their legal representative may enroll in the Copay Program either by enrolling in Adbry Advocate or via other means provided by LEO Pharma, such as via the Product website or via specialty pharmacies contracted with LEO Pharma to dispense the Product.

Eligibility Requirements and Limitations

- The current annual maximum benefit available under the Program is thirteen thousand U.S. dollars ($13,000.00) per eligible patient.
- The patient must be 12 years of age or older with a valid prescription for an approved use of the Product.
- The patient must be a resident of the United States or Puerto Rico.
- The patient must have commercial insurance, either directly or through dependent coverage.
- The patient must not have prescription drug coverage for the Product, in whole or in part, either directly or through dependent coverage, under any federal or state health program that is a "federal healthcare program" as defined under 42 U.S.C. § 1320a-7b(f), including but not limited to Medicare, Medicaid, TRICARE, the Indian Health Service, the Department of Veterans Affairs Health Benefit Program, state Children's Health Insurance Programs under the Title XIX or Title XXI of the Social Security Act, state block grant programs under Title V or Title XX of the Social Security Act, or state pharmaceutical assistance programs. This Program is not available for patients within a deductible or similar cost-sharing periods under such federal healthcare programs.
- Uninsured and cash-paying patients are not eligible.

Additional Terms and Conditions

- The Program does not constitute insurance.
- The availability of benefits under the Program does not constitute any guarantee of coverage under any prescription benefit insurance or program.
- The benefits under this Program may not be combined with any third-party rebate, coupon, or offer.
- By submitting a request for benefits under the Program or by participating in the Program, the HCP acknowledges and agrees that the HCP: (1) will not submit any claim or other request for payment or reimbursement for benefits provided under the Program to the patient or any third-party plan or program, including any commercial or government assistance program; and (2) will advise the patient that the patient may not submit a claim to any third-party plan or program but should report their receipt of benefits to the patient's insurer if required by their plan.
- By submitting a request for benefits under the Program or by participating in the Program, the patient (or their legal representative) acknowledges and agrees that the patient: (1) will not submit any claim or other request for payment or reimbursement for benefits provided under the Program to any third-party plan or program, including any commercial or government assistance program; and (2) will report their receipt of benefits to their insurer if required by their plan.
- Patients and/or their HCPs must submit complete information and/or documentation required under the Program and attest to the truthfulness and accuracy of the information and/or documentation.
- By submitting a request for benefits under the Program or by participating in the Program, the patient (or their legal representative) and HCP individually acknowledge, understand, and agree to the benefit, eligibility, and other program limitations, terms, and conditions as set forth herein.
- The availability of benefits under the Program is not conditioned on any past, present, or future purchase, including any potential future refills of Product.
- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") grants individuals rights related to their Protected Health Information ("PHI"). To the extent LEO Pharma receives PHI about you, we will use and disclose it according to the patient authorization that you (or legal representative) have completed for your HCP in connection with the LEO Pharma Adbry Advocate Program. For more information about how your PHI is used and disclosed by your HCP, please review your HCP's Notice of Privacy Practices. To the extent LEO Pharma collects personal data about you that is not PHI, we will use and disclose that personal data as disclosed in our privacy policy, available at Privacy Policy | LEO Pharma (leo-pharma.us). By participating in the LEO Pharma Adbry Advocate Program, you acknowledge that we may collect health information from you, which may be considered "sensitive" data under some U.S. state laws. Moreover, if you are a parent or guardian of a minor participating in the program, you (or legal representative) acknowledge that we may collect data about the participating minor/s, which may also be considered "sensitive" data under some U.S. state laws.
- The copay card, whether issued virtually or physically, has no cash value.
- Offer void where prohibited by law, taxed, or restricted.
- LEO Pharma has sole discretion to determine Program eligibility.
- LEO Pharma may unilaterally amend, modify, or terminate Program benefits and eligibility criteria at any time and without notice.

Continued

ADBRY® PATIENT ASSISTANCE PROGRAM – PROGRAM SUMMARY AND TERMS & CONDITIONS

LEO Pharma Inc. ("LEO Pharma") is the distributor of Adbry® (tralokinumab-ldrm) injection (the "Product"). LEO Pharma sponsors the Adbry® Advocate™ patient access programs ("Adbry Advocate") which are operated by LEO Pharma's designated service provider ("LEO Service Provider"). The purpose of Adbry Advocate is to help ensure that medically appropriate patients have access to the medication that has been prescribed for them by their treating healthcare provider ("HCP").

One of the offerings available for the benefit of patients under Adbry Advocate is the Adbry® Patient Assistance Program (the "Program" or "PAP"). Under the Program, Adbry Advocate will provide the Product, without charge, to patients who: a) demonstrate financial need; and b) do not have insurance for the Product or who are underinsured, and who otherwise satisfy the eligibility requirements for the Program. Adbry Advocate will provide the Product without charge to eligible patients on a periodic basis and consistent with the prescribing information for the Product. A patient or their legal representative may enroll in the Program by completing, signing, and submitting the applicable portion of the Adbry Advocate Program Enrollment and Prescription Form. An HCP may prescribe the Product by completing, signing, and submitting the applicable portion of the Enrollment and Prescription Form which includes a prescription for the Product that will be processed by a non-commercial dispensing pharmacy ("NCDP") affiliated with the LEO Service Provider. Alternatively, a patient's HCP may e-prescribe the Product directly to the NCDP, provided the HCP has completed, signed, and submitted an annual Healthcare Provider eRx Program Certification Form. If the HCP e-prescribes the Product directly to the NCDP, the patient, or their legal representative must complete, sign, and submit a patient authorization and any other information reasonably requested by the Program in order for Adbry Advocate to verify eligibility and for the patient to receive assistance under the Program. A patient requesting assistance under the PAP (or their legal representative) is also required to submit information and documentation concerning household size and income and insurance status to allow Adbry Advocate to evaluate the patient's eligibility under the Program.

After the prescription is received by the NCDP and the patient's eligibility for the Program is verified, the Product may be delivered to the prescribing HCP's office. Alternatively, if: a) the HCP decides that the patient or caregiver may properly inject the Product; and b) the patient or caregiver received training on the proper preparation and injection of the Product, then the Product may be delivered to the patient's address of record or other location mutually agreed upon by Adbry Advocate and the patient or patient's caregiver. In the event of delivery to the patient's address of record or other mutually agreed upon location, Adbry Advocate will coordinate the shipment of the Product, which may extend the delivery time. Product will be dispensed from the NCDP via overnight delivery.

Eligibility Requirements and Limitations

- The patient must be 12 years of age or older with a valid prescription for the Product.
- The patient must be a resident of the United States or Puerto Rico.
- The patient's annual household income must be less than or equal to four hundred percent (400%) of the federal poverty level for the applicable household size.
- The patient either: (a) has Medicare Part D coverage and has applied for and been denied the Low Income Subsidy ("LIS") from the Social Security Administration and meets the further conditions below; or (b) has no insurance coverage, no benefits for prescription medicines, or the patient's insurance plan has formally denied coverage for the Product through a written coverage policy or a written decision as part of a benefits inquiry or prior authorization process and has provided a copy of the denial.
- The patient must not have insurance coverage for the Product, in whole or in part, either directly or through dependent coverage, under any federal or state government-subsidized health program that is a "federal healthcare program" as defined under 42 U.S.C. § 1320a-7b(f), including, but not limited to, Medicare, Medicaid, TRICARE, the Indian Health Service, the Department of Veterans Affairs Health Benefits, state Children's Health Insurance Programs under the Title XIX or Title XXI of the Social Security Act, state block grant programs under Title V or Title XX of the Social Security Act, or state pharmaceutical assistance programs, except that, if the patient is a Medicare Part D enrollee, the patient may be eligible if the patient has applied for and been denied the LIS and meets the further conditions below. This Program is not available for patients within a deductible or similar cost-sharing periods under such federal healthcare programs.
- If the patient is a Medicare Part D enrollee that has been denied the LIS, the patient is subject to the following additional conditions in order to receive assistance under the Program: (1) the patient shall not submit any claim for reimbursement for the Product to any third party, including a Medicare Part D plan or another public or private plan or program, during the period of assistance; (2) the cost of the Product shall not apply or be applied toward the patient's Medicare Part D True Out-of-Pocket Costs; (3) the patient must inform their Medicare Part D plan about enrollment in the Program and that the patient will receive the Product for free under the Program for the remainder of the coverage year; (4) the patient must spend at least four percent (4%) of their annual household income on prescription medications covered through the Part D plan in the current calendar year; and (5) the patient must receive free Product through the Program through the end of the calendar year in which assistance is first provided, even if the patient's use of the Product is periodic during the year.
- Eligible patients without Medicare Part D coverage will receive up to twelve (12) months of Product without charge from the date of enrollment. Eligible patients with Medicare Part D coverage will receive Product through the end of the coverage year. Annual re-enrollment is required.
- If the patient may be eligible for Medicaid, either directly or through dependent coverage, then the patient (or their legal representative) is required to provide documentation of Medicaid denial before being assessed for Program eligibility.

Additional Terms and Conditions

- The Program does not constitute insurance.
- The provision of Product does not constitute any guarantee of coverage under any prescription benefit insurance or program.
- By submitting a request for Product under the Program or by participating in the Program, the HCP acknowledges and agrees that the HCP: (1) will not submit any claim or other request for payment or reimbursement for Product provided under the Program to the patient or any third-party plan or program, including any commercial or government assistance program; (2) will advise the patient that the patient may not submit a claim to any third-party program or plan but should report their receipt of Product to the patient's insurer if required by their plan; (3) will dispense or administer Product solely to the eligible patient for whom such Product was requested; and (4) will not sell, transfer, or otherwise dispense Product to any other third party.
- By submitting a request for Product under the Program or by participating in the Program, the patient (or their legal representative) acknowledges and agrees that the patient: (1) will not submit any claim or other request for payment or reimbursement for Product provided under the Program to any third-party plan or program, including any commercial or government assistance program; (2) will report their receipt of Product to their insurer if required by their plan; and (3) will not sell, transfer, or otherwise dispense Product to any other third party.
- The NCDP only dispenses Product pursuant to the Adbry Advocate patient access programs. Product prescriptions subject to third-party insurance, including refill prescriptions, may be dispensed by the pharmacy of the patient's choice, subject to product distribution and third-party payer limitations.
- Patients and/or their HCPs must submit complete information and/or documentation required under the Program and attest to the truthfulness and accuracy of the information and/or documentation.
- By submitting a request for Product under the Program or by participating in the Program, the patient (or their legal representative) and the HCP individually acknowledge, understand, and agree to the benefit, eligibility, and other program limitations, terms, and conditions as set forth herein.

Continued

ADBRY® PATIENT ASSISTANCE PROGRAM (CONT'D)

- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") grants individuals rights related to their Protected Health Information ("PHI"). To the extent LEO Pharma receives PHI about you, we will use and disclose it according to the patient authorization that you (or legal representative) have completed for your HCP in connection with the LEO Pharma Adbry Advocate Program. For more information about how your PHI is used and disclosed by your HCP, please review your HCP's Notice of Privacy Practices. To the extent LEO Pharma collects personal data about you that is not PHI, we will use and disclose that personal data as disclosed in our privacy policy, available at Privacy Policy | LEO Pharma (leo-pharma.us). By participating in the LEO Pharma Adbry Advocate Program, you (or legal representative) acknowledge that we may collect health information from you, which may be considered "sensitive" data under some U.S. state laws. Moreover, if you are a parent or guardian of a minor participating in the program, you acknowledge that we may collect data about the participating minor/s, which may also be considered "sensitive" data under some U.S. state laws.
- The availability of Product under the Program is not conditioned on any past, present, or future purchase, including any potential future refills of Product.
- Offer void where prohibited by law, taxed, or restricted.
- LEO Pharma has sole discretion to determine Program eligibility.
- LEO Pharma may unilaterally amend, modify, or terminate Program benefits and eligibility criteria at any time and without notice.

References: a. Dupixent: pharmacy prior authorization request form. Aetna. Accessed June 5, 2024. https://www.aetnabetterhealth.com/content/dam/aetna/medicaid/illinois/providers/pdf/Dupixent-Request-Form-IL-4.1.2020-ua.pdf **b.** Cigna national formulary coverage policy: drug quantity management—per days: immunologicals—Adbry™ (tralokinumab-ldrm subcutaneous injection). Cigna. February 1, 2023. Accessed June 5, 2024. https://static.cigna.com/assets/chcp/pdf/coveragePolicies/cnf/cnf_717_coveragepositioncriteria_immunologicals_adbry_dqm_per_days.pdf **c.** Anthem.com. Clinical Criteria. Accessed June 5, 2024. https://files.providernews.anthem.com/1651/ING-CC-0208.pdf **d.** BlueCross BlueShield Federal Employee Program 5.90.53. Accessed June 5, 2024. https://www.fepblue.org/-/media/PDFs/Medical%20Policies/07-06-2022/July-Pharmacy-New/59053%20Adbry%20tralokinumabldrm.pdf **e.** Request for prior authorization tralokinumab-ldrm (Adbry). Molina Healthcare. Accessed June 5, 2024. https://www.molinahealthcare.com/providers/ia/medicaid/resources/-/media/Molina/PublicWebsite/PDF/Providers/ia/IA_Pharmacy_Forms/adbry-pa-form-npi-oct-2022_remediated **f.** UnitedHealthcare pharmacy clinical pharmacy programs: Adbry™ (tralokinumab-ldrm). June 1, 2023. Accessed June 5, 2024. https://www.uhcprovider.com/content/dam/provider/docs/public/prior-auth/drugs-pharmacy/commercial/a-g/PA-Med-Nec-Adbry.pdf **g.** Prescription & enrollment form: Adbry™ (tralokinumab-ldrm). Accredo. Accessed June 51, 2024. https://accredo.com/prescribers/referral_forms/adbry.pdf

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

Please click here for Full Prescribing Information.

Adbry® advocate™

Support for your patients, your way

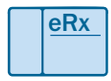
1 Submit the Enrollment Form (EF) or the prescription directly to an Adbry® in-network SP[a]

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

Click here to view support services available with each option.
Click here for Full Terms, Conditions, and Eligibility Rules. Restrictions apply.

Options for submitting the EF to the Adbry Advocate Program

Fax the EF to:
855-423-0011



ePrescribe in your EHR:
Select **PharmaCord**

NCPDP: 1836191 NPI: 1699202838

To submit the HCP eRx Program Certification Form, scan the QR code (on previous page) for annual certification, or fax a copy, available from the FRM, to 855-423-0011.

Enroll online at:
Adbryhcp.com/support-and-resources

Adbry Advocate Program contact information:

Phone: 1-844-MYADBRY (1-844-692-3279)
Hours: 8am–8pm ET
Email: info@adbry-advocate.com

Name	
Title	
Email	
Phone	

[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.

Click here for Full Important Safety Information.

Click here for Full Prescribing Information.

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