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

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 health care 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 adult patients 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, International Classification of Diseases; 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/mL

Adbry™ advocate™

Support for your patients, your way

May offer patients access to a range of patient services

1 Submit directly to the Adbry™ Advocate™ Program — eligible, commercially insured patients may have access to a range of services, including the Adbry™ Rapid Access™ Program that can provide a free initial dose within approximately 48 hours[a,b,c]

- **Fax** the Enrollment and Prescription Form (EPF) to the Adbry Advocate Program at **855-423-0011**

2 Dual Submission — eligible, commercially insured patients may have access to a range of services, including the Rapid Access Program[a,b,c]

- Submit to both a specialty pharmacy (SP) in the contracted SP network **and** the Adbry Advocate Program, which will monitor the progress of the benefits investigation and prior authorization at the SP through a data link. The Program will also coordinate with the SP to avoid duplication, and follow up only as needed[d]

3 Submit the EPF or the prescription to a contracted SP

- Fax the EPF or your prescription form to a SP in the contracted SP network. A list of these SPs is available from the Field Reimbursement Manager (FRM)[d]
- Patients may be eligible to receive a more limited range of services[e]

Click here for details.

If requested, the FRM or Case Manager can help track your patient's benefits investigations and prior authorizations if the prescription is submitted through the Adbry Advocate Program.

[a] The initial dose of Adbry may be shipped either to your office or the patient, after submission of a completed Enrollment and Prescription Form. A Nurse Advocate must 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] Additional terms, conditions and eligibility rules apply. Submission of a completed Enrollment and Prescription Form is required. Patient or health care 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] Patient is not eligible for the Program if enrolled in any federally or state funded health care program, including but not limited to Medicare (including Medicare Part D), Medicaid, VA, DOD, TRICARE or CHIP.

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

[e] SPs may refer eligible, commercially insured patients to the Adbry Advocate Program for enrollment in the Rapid Access and Bridge Care Programs.

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

Click here for Full Important Safety Information.

Click here for Full Prescribing Information.

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

Adbry™ advocate™

Support for your patients, your way

Comprehensive patient support programs

Access, Savings, and Support Services

- **Adbry™ Rapid Access™ Program:** A free initial dose for eligible, commercially insured patients[a,b,c]
- **Adbry™ Bridge Care™ Program:** Eligible, commercially insured patients may receive free drug for up to 2 years or until commercial access is secured, whichever happens earlier[b,c]
- **Adbry Copay Program:** For eligible, commercially insured patients. Restrictions apply[b,c,*]
- **Adbry Patient Assistance Program:** Eligible patients with demonstrated financial need and with limited or no prescription coverage may be able to receive therapy without charge[b,d]

Benefits Investigation

- The benefits investigation is conducted efficiently to get patients onto their prescribed therapy as quickly as possible. And when you submit through the Adbry™ Advocate™ Program or through a dual submission, it is seamlessly coordinated to avoid duplication of SP services

Patient Nursing Support

- The patient's Nurse Advocate will welcome, motivate, offer support to, and answer nonclinical questions from patients through their treatment journey. Nurse Advocates cannot provide any medical advice and must refer patients to seek the advice of their health care provider
- The Adbry Advocate Program can also provide supplemental patient injection training (in-home and virtual options)[b]

Your patients can stay connected with Adbry™ Digital Companion

- We've partnered with Medisafe so patients can stay connected with their support services, their Nurse Advocate, and access educational resources

Medisafe is a registered trademark of Medisafe Project LTD.

[a] The initial dose of Adbry may be shipped either to your office or the patient, after submission of a completed Enrollment and Prescription Form. A Nurse Advocate must 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] Additional terms, conditions and eligibility rules apply. Enrollment in Adbry Advocate is not required to obtain copay support. For all other patient support programs, submission of a completed Enrollment and Prescription Form is required. Patient or health care 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] Patient is not eligible for the Program if enrolled in any federally or state funded health care program, including but not limited to Medicare (including Medicare Part D), Medicaid, VA, DOD, TRICARE or CHIP.

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

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

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

Click here for Full Important Safety Information.

Click here for Full Prescribing Information.

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

Adbry™ advocate™

Flexible options

Services available for each initiation option[a]

	Rapid Access™ Program[a,b,c]	Bridge Care™ Program[a,c]	Supplemental injection training	Copay Program[a,c,*]	PAP[a,d]	BI + PA	Appeals support	Ongoing nursing support	Medisafe app
To Adbry™ Advocate™ Program via Fax	●	●	●	●	●	●	●	●	●
Dual Submission: Adbry Advocate Program + SP[e]	●	●	●	●	●	●	●	●	●
SP only[e]	—	—	●	●	—	●	O[f]	●	●
A noncontracted SP	—	—	—	—	—	—	—	—	—

Click here for Full Terms, Conditions, and Eligibility Rules. [e]A contracted SP. [f]O=Level of appeals support may vary.

The Enrollment and Prescription Form is available at: AdbryHCP.com

Fax the Enrollment and Prescription Form to: 855-423-0011

Adbry Advocate Program contact information:

Phone: 1-844-MYADBRY (1-844-692-3279)

Hours: 8am–8pm ET

Fax: 855-423-0011

Email: info@adbry-advocate.com

Medisafe is a registered trademark of Medisafe Project LTD.

[a] Additional terms, conditions and eligibility rules apply. Enrollment in Adbry Advocate is not required to obtain copay support. For all other patient support programs, submission of a completed Enrollment and Prescription Form is required. Patient or health care 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.

[b] The initial dose of Adbry may be shipped either to your office or the patient, after submission of a completed Enrollment and Prescription Form. A Nurse Advocate must 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.

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

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

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

PAP, Adbry Patient Assistance Program; BI, Benefits Investigation; PA, Prior Authorization; SP, Specialty Pharmacy.

Click here for Full Important Safety Information.

Click here for Full Prescribing Information.

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

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]

Diagnosed by, or in consultation with dermatologist, allergist, or immunologist[b,e,g]

Some plans may request medical records along with applicable labs and tests supporting the diagnosis[a,d,e]

Baseline evaluation:
- Body Surface Area (BSA) ≥10% or, if <10%, a description of sensitive areas involved[d,e,g]

Some plans may request use of an additional scoring tool, such as[d]:
- Investigator's Global Assessment (IGA)[a,e]
- Eczema Area and Severity Index (EASI)[e]
- Patient-Oriented Eczema Measure (POEM)[a]
- Scoring Atopic Dermatitis (SCORAD) index

Some plans may request a letter of medical necessity (LMN)[e,f]

Common step-edit criteria

Failure, contraindication, or intolerance to **1 or more of the following** therapeutic classes of topical therapies (document drug, date of trial, and/or contraindication to medication)[a-e,g]:
- Medium-to-very high potency topical steroid
- Topical calcineurin inhibitor
- Topical PDE4 inhibitor[f]

Some plans may require trials of a specific duration.[b,c]

Some plans may require trial and documented failure on:
Phototherapy[c,e]
or
Systemic treatment, such as immunosuppressants[a-c,e]

Criteria based on information from national and regional plans and PBMs for a biologic approved for the treatment of moderate-to-severe atopic dermatitis as of March 2021.

Click here for references.

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	Enter date

Criteria:

Type in plan name	Enter date

Criteria:

Type in plan name	Enter date

Criteria:

Type in plan name	Enter date

Criteria:

A FRM may be able to help provide this information.

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

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

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, and date of birth, height, and weight
- Provider name, specialty, NPI#, contact information

Diagnosis

- Diagnosis (click here for 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

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

NPI, National Provider Identifier.

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 health care 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; NPI, National Provider Identifier; SCORAD, Scoring Atopic Dermatitis; POEM, Patient-Oriented Eczema Measure.

Click here for Full Important Safety Information.

Click here for Full Prescribing Information.

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

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 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,

_____

[Health care provider's name, signature, and contact information]

Double-click to open Word version of this letter.

Click here for Full Important Safety Information.

Click here for Full Prescribing Information.

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

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

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

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

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,

_____
[Health care 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.

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

EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NPI, National Provider Identifier; 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

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,

_____

[Health care provider's name, signature, and contact information]

Double-click to open Word version of this letter.

Enc: Adbry Prescribing Information
Medical records

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

EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NPI, National Provider Identifier; 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

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

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

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 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 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.

_____

[Health care provider's name, signature, and contact information]

Enc: Adbry Prescribing Information, Medical records

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

EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NPI, National Provider Identifier; 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 health care 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 health care 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.

Click here for Full Important Safety Information.

Click here for Full Prescribing Information.

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

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,

_____ _____

[Health care 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.

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

6 Suggestion for Preparing a 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,

_____

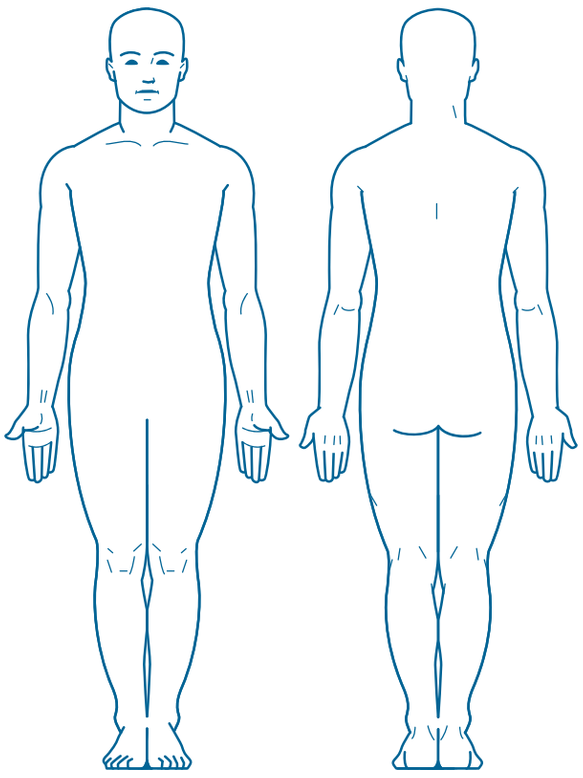
[Your name, signature, and contact information]

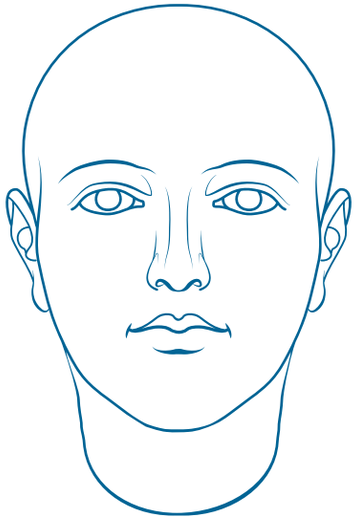
Double-click to open Word version of this letter.

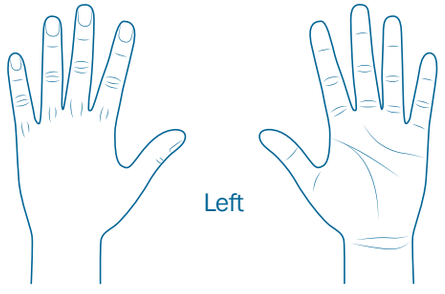
Click here for Full Important Safety Information.

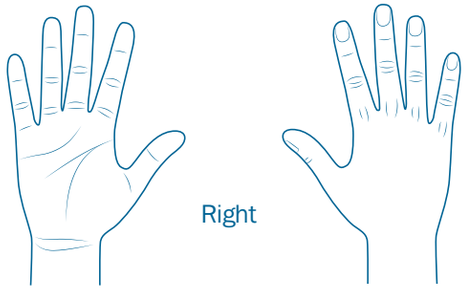
Click here for Full Prescribing Information.

Body diagrams









ICD-10 Codes[a]

Information you submit to health care 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.

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

[a] ICD10Data.com. Atopic dermatitis. Accessed March 17, 2021. https://www.icd10data.com/ICD10CM/Codes/L00-L99/L20-L30/L20-

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)

Click here for Full Important Safety Information.

Click here for Full Prescribing Information.

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

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 service provider – PharmaCord LLC. 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.

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 that have been prescribed the Product for an approved use and who meet the Program eligibility criteria. A patient may enroll in the Program by completing, signing, and submitting the applicable portion of the Adbry Advocate Program Enrollment and Prescription Form. A healthcare provider ("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 the non-commercial dispensing pharmacy (NCDP) affiliated with PharmaCord LLC.

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 give injections of the Product; and b) the patient or caregiver has 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 18 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.
- The patient must not have prescription drug coverage for the Product, in whole or in part, 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 healthcare provider acknowledges and agrees that he or she: (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 he or she may not submit a claim to any third-party plan or program but should report his or her receipt of Product to the patient's insurer if required by his or her 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 acknowledges and agrees that he or she: (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 his or her receipt of Product to his or her insurer if required by his or her 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 healthcare providers 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, each of the patient and the healthcare provider acknowledges, understands and agrees 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.
- 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 service provider – PharmaCord LLC. 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.

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 the prescribing information for the Product, without charge and on a periodic basis, to commercially insured patients that have been prescribed the Product for an approved use and who satisfy the Program's eligibility criteria, after experiencing an initial delay, as defined below, in securing a determination of insurance coverage for the Product. A patient may enroll in the Program by completing, signing, and submitting the applicable portion of the Adbry Advocate Program Enrollment and Prescription Form. A healthcare provider ("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 the non-commercial dispensing pharmacy (NCDP) affiliated with PharmaCord LLC.

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 a caregiver may properly give injections of the Product; and b) the patient or caregiver has 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 18 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.
- The patient must not have prescription drug coverage for the Product, in whole or in part, 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 either:
  - A delay of more than five (5) 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 (e.g., 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 (e.g., due to a change in employment) — for which an 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, without charge, on a periodic basis, to such patient for up two (2) years or until the 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 healthcare provider acknowledges and agrees that he or she: (1) will not submit any claim or other request for payment or reimbursement for Product provided under the Program to the patient or any plan or program, including any commercial or government assistance program; (2) will advise the patient that he or she may not submit a claim to any third-party program or plan but should report his or her receipt of Product to the patient's insurer if required by his or her 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 acknowledges and agrees that he or she: (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 his or her receipt of Product to his or her insurer if required by his or her 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 healthcare providers 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, each of the patient and the healthcare provider acknowledges,

Continued

ADBRY™ BRIDGE CARE™ PROGRAM (CONT'D)

understands and agrees 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.
- 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 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 service provider – PharmaCord LLC. 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.

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 sole discretion of the Program. 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 may enroll in the Copay Program either through 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 fifteen thousand dollars ($15,000.00) per eligible patient.
- The patient must be 18 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.
- The patient must not have prescription drug coverage for the Product, in whole or in part, 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 healthcare provider acknowledges and agrees that he or she: (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 he or she may not submit a claim to any third-party plan or program but should report his or her receipt of benefits to the patient's insurer if required by his or her plan.
- By submitting a request for benefits under the Program or by participating in the Program, the patient acknowledges and agrees that he or she: (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 his or her receipt of benefits to his or her insurer if required by his or her plan.
- Patients and/or their healthcare providers 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, each of the patient and healthcare provider acknowledges, understands and agrees 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 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 reserves the right to amend, modify, or terminate Program benefits and eligibility criteria at any time and without notice.

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 is operated by LEO Pharma's service provider – PharmaCord LLC. 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.

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 may enroll in the Program by completing, signing, and submitting the applicable portion of the Adbry Advocate Program Enrollment and Prescription Form. A healthcare provider ("HCP") may prescribe

Continued

ADBRY™ PATIENT ASSISTANCE PROGRAM (CONT'D)

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 the non-commercial dispensing pharmacy (NCDP) affiliated with PharmaCord LLC. A patient requesting assistance 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 a caregiver may properly give injections of the Product; and b) the patient or caregiver has 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 18 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 income must be less than or equal to 600% 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, 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 ("TrOOP"); (3) the patient must inform his/her 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 his or her 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 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, then the patient 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 healthcare provider acknowledges and agrees that he or she: (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 he or she may not submit a claim to any third-party program or plan but should report his or her receipt of Product to the patient's insurer if required by his or her 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 acknowledges and agrees that he or she: (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 his or her receipt of Product to his or her insurer if required by his or her 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 healthcare providers 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, each of the patient and the healthcare provider acknowledges, understands and agrees 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.
- 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™ IN-HOME INJECTION TRAINING 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 service provider – PharmaCord LLC. 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.

One of the offerings available for the benefit of patients under Adbry Advocate is the Adbry In-Home Injection Training Program (the "Program"). In order to help ensure the proper and safe administration of the Product, under the Program, Adbry Advocate, through its contracted service provider, Market Dynamics, will arrange for the services of a licensed nurse to provide in-home injection training for the Product, without charge, to patients 18 years of age or older with a valid prescription for an approved use for the Product and who otherwise satisfy the eligibility requirements for the Program. A patient may enroll in the Program by completing, signing, and submitting the applicable portion of the Adbry Advocate Program Enrollment and Prescription Form. For eligible patients, PharmaCord will coordinate and verify the scheduling of the in-home training visit with Market Dynamics.

Eligibility Requirements and Limitations

- The patient must be 18 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 Program will provide a single in-home injection training visit. A second in-home training visit may be provided for patients who require additional training. Additional injection video or "virtual" training programs and support (e.g., "virtual" training via PharmaCord and video training available on the Product website) are available through Adbry Advocate
- The Program provides in-home injection training only. Neither Adbry Advocate nor Market Dynamics will administer injections to any patient under any circumstances.
- Adbry Advocate or Market Dynamics each reserves the right to cancel or reschedule in-home training visits in its sole discretion on the basis of public health or security considerations.

Additional Terms and Conditions

- The Program does not constitute insurance.
- The provision of services under the Program does not constitute any guarantee of coverage under any prescription benefit insurance or program.
- By submitting a request for services under the Program or by participating in the Program, the healthcare provider acknowledges and agrees that he or she: (1) will not submit any claim or other request for payment or reimbursement for services 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 he or she may not submit a claim to any third-party program or plan but should report his or her receipt of services to the patient's insurer if required by his or her plan.
- By submitting a request for services under the Program or by participating in the Program, the patient acknowledges and agrees that he or she: (1) will not submit any claim or other request for payment or reimbursement for services provided under the Program to any third-party plan or program, including any commercial or government assistance program; (2) will report his or her receipt of services to his or her insurer if required by his or her plan; (3) consents to the admission of the in-home training nurse to his or her premises for the purpose of administering the training; and (4) will comply with Program procedures designed to promote public health and safety of in-home training personnel, including but not limited to such procedures or requirements as may be appropriate to minimize the potential spread of the COVID-19 virus.
- Patients and/or their healthcare providers 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 services under the Program or by participating in the Program, each of the patient and the healthcare provider acknowledges, understands and agrees to the benefit, eligibility, and other program limitations, terms and conditions as set forth herein.
- The availability of services 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 amend, modify, or terminate Program benefits and eligibility criteria at any time and without notice.

References: a. Aetna. Dupixent Pharmacy Prior Authorization Request Form. Accessed March 17, 2021. https://www.aetnabetterhealth.com/content/dam/aetna/medicaid/illinois/providers/pdf/Dupixent-Request-Form-IL-4.1.2020-ua.pdf **b.** Cigna Drug and Biologic Coverage Policy. Dupilumab. Accessed March 17, 2021. https://static.cigna.com/assets/chcp/pdf/coveragePolicies/pharmacy/ph_1810_coveragepositioncriteria_dupilumab.pdf **c.** Anthem.com. Clinical Criteria: Dupixent (dupilumab). Accessed March 17, 2021. https://www.anthem.com/ca/ms/pharmacyinformation/Dupixent.pdf **d.** BlueCross BlueSheild Federal Employee Program. Dupixent Prior Approval Request. Accessed March 17, 2021. https://www.caremark.com/portal/asset/FEP_Form_Dupixent.pdf **e.** Molina Healthcare. Recommendations/Coverage Criteria. Accessed March 17, 2021. https://www.molinahealthcare.com/~/media/Molina/PublicWebsite/PDF/providers/wa/medicaid/resource/dupixent-dupilumab-mcp296.pdf **f.** UnitedHealthcare. UnitedHealthcare Pharmacy Clinical Pharmacy Programs. Accessed March 17, 2021. https://www.uhcprovider.com/content/provider/en/viewer.html?file=%2Fcontent%2Fdam%2Fprovider%2Fdocs%2Fpublic%2Fresources%2Fpharmacy%2Fstep-therapy%2FStep-Therapy-Dupixent.pdf **g.** Accredo. Prescription and Enrollment Form: Dupixent (dupilumab). Accessed March 17, 2021. https://accredo.com/prescribers/referral_forms/dupixent.pdf

INDICATION

ADBRY™ (tralokinumab-ldrm) injection is indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients 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 health care 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 in patients treated 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 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:** The safety and effectiveness of ADBRY have not been established in pediatric patients.

Please click here for Full Prescribing Information.

Adbry™ advocate™

Support for your patients, your way

Adbry™ Advocate™ Program contact information:

Phone: 1-844-MYADBRY (1-844-692-3279)

Hours: 8am–8pm ET

Fax: 855-423-0011

Email: info@adbry-advocate.com

HCP website: AdbryHCP.com

Consumer website: Adbry.com

Fax the Enrollment and Prescription Form (EPF) to:
855-423-0011

Please contact me if you have any questions

Name	
Title	
Email	
Phone	

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

Click here for Full Important Safety Information.

Click here for Full Prescribing Information.