accessDAXXIFY™

Sample Letter of Medical Necessity

The following pages may be customized to use as a letter of medical necessity for DAXXIFY® (daxibotulinumtoxinA). Please note that the Important Safety Information does not need to be included as part of your letter.

The attached letter provides an example of the types of information that may be provided to insurers when responding to a request from a patient's insurance company to provide a letter of medical necessity for DAXXIFY®. The sample letter is intended to be used as a guide. Information contained in this letter should not be construed as medical or legal advice and does not guarantee how to submit any specific form for coverage or payment.

The treating physician is responsible for information contained in this letter and should be modified to the specific needs of your patient and address the reason(s) why DAXXIFY® is the appropriate treatment option. You should always include pertinent clinical information that supports your decision to prescribe DAXXIFY®.

A copy of the full Prescribing Information for DAXXIFY® is available at www.revance.com. Use of the information in the attached letter does not guarantee that the insurance company will provide coverage or reimbursement for DAXXIFY® and is not intended to be a substitute for or an influence on the independent medical judgment of the physician.

Please consider the following information when developing and submitting a letter of medical necessity:

Check with the health plan directly to confirm coverage for individual patients.

- Review the health plan's medical policy and confirm coverage criteria for your patient
- Provide clinical background on your patient's condition and clearly state your patient's individual circumstances to justify why DAXXIFY® is medically necessary
- Provide clinical justification and include copies of relevant clinical data to support your decision (eg, office notes, product insert, etc)
- Submit the letter as required by the health plan and state guidelines. It is important that you understand the process for each health plan, including how to submit the request (fax, phone, email, the company's website, etc) as well as how and when the decision will be communicated
- Track the status of your request and follow up with the health plan as needed

DAXXIFY® daxibotulinumtoxinA-lanm injection | REVANCE® THERAPEUTICS

Please see Important Safety Information, including Indication and BOXED WARNING on the next page.

INDICATION

DAXXIFY® (daxibotulinumtoxinA-lanm) injection is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment of cervical dystonia in adults.

WARNING: DISTANT SPREAD OF TOXIN EFFECT

The effects of DAXXIFY® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. DAXXIFY® is not approved for the treatment of spasticity or any conditions other than cervical dystonia and glabellar lines.

IMPORTANT SAFETY INFORMATION

Contraindications

DAXXIFY® contraindications include hypersensitivity to any botulinum toxin preparation or any of the components in the formulation and infection at the injection site(s).

Warnings and Precautions

Please refer to Boxed Warning for Distant Spread of Toxin Effect.

The potency units of DAXXIFY® are not interchangeable with preparations of other botulinum toxin products. Recommended dose and frequency of administration should not be exceeded. Patients should seek immediate medical attention if respiratory, speech or swallowing difficulties occur. Use caution when administering to patients with pre-existing cardiovascular disease. Concomitant neuromuscular disorders may exacerbate clinical effects of treatment.

Adverse Reactions

The most commonly observed adverse reactions (≥5%) were headache (9%), injection site pain (8%), injection site erythema (5%), muscular weakness (5%), and upper respiratory tract infection (5%).

Drug Interactions

Co-administration of DAXXIFY® and aminoglycoside antibiotics, anticholinergic agents or any other agents interfering with neuromuscular transmission or muscle relaxants should only be performed with caution as the effect of DAXXIFY® may be potentiated. The effect of administering different botulinum neurotoxins during course of treatment with DAXXIFY® is unknown.

Use in Specific Populations

DAXXIFY® is not recommended for use in children or pregnant women.

Please see DAXXIFY® full Prescribing Information, including Boxed Warning and Medication Guide.

To report side effects associated with DAXXIFY®, please visit safety.revance.com or call 1-877-373-8669. You may also report side effects to the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

DAXI-004725

[Insert Date]

Request for DAXXIFY® (daxibotulinumtoxinA-lanm) for Cervical Dystonia

RE: [Patient Name]
[Patient Insurance ID Number]
[Patient Date of Birth]

To Whom it May Concern:

This letter of medical necessity is in support of my request to treat [Patient Name] with DAXXIFY® (daxibotulinumtoxinA-lanm), a United States Food and Drug Administration (FDA)-approved therapy indicated for the treatment of patients with cervical dystonia. The full Prescribing Information for DAXXIFY® can be accessed at www.revance.com.

SUMMARY OF PATIENT'S MEDICAL HISTORY AND DIAGNOSIS

As a board-certified [field of certification] with [XX] years of experience treating cervical dystonia, I believe that DAXXIFY® is medically necessary for my patient. [HCP to state their opinion on the medical necessity of treating with DAXXIFY®.]

I have evaluated my patient's clinical symptoms and have provided a summary below:

- [Patient Name] is [Age] years old and was initially diagnosed with cervical dystonia [ICD-10-CM] on [Date].
- [Any imaging data]
- This patient has a diagnosis of cervical dystonia as evidenced by: (may include)
    1. Patient's cervical dystonia is associated with sustained head tilt or abnormal posturing with limited range of motion in the neck;
    2. The patient has a history of recurrent involuntary contraction(s) of one or more of the muscles of the neck (eg, sternocleidomastoid, splenius, trapezius, or posterior cervical muscles);
- [A complete description of the site(s) injected and dosing]
- [Provide a discussion of the patient's clinical history, current symptoms and condition, any potential contraindications]

Based on the patient's clinical condition and a review of the supporting documentation, I am confident you will agree that DAXXIFY®, which is clinically indicated for this condition, is the appropriate treatment option. To enable me to provide the appropriate care for my patient, it is important that adequate coverage for DAXXIFY® is provided.

Please call me at [Phone Number] if I can be of further assistance or if you require additional information.
Thank you in advance for your immediate attention to this request.

Sincerely,

[Treating physician's signature]
[Treating physician's name, MD/DO]

Enclosures (suggested):
Chart notes
Test results
Supporting medical studies
DAXXIFY® Prescribing Information