

Coverage and Chart Documentation Checklist

Considerations for Tyrvaya[®]

COMMON INFORMATION NEEDED FOR PRIOR AUTHORIZATION (PA) AND OTHER COVERAGE REQUESTS

This checklist contains common Prior Authorization requirements seen in practice and may not consist of everything required by an insurance plan. Thus, the content provided in this guide is for informational purposes and is not intended as legal advice or to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure that Tyrvaya claims are accurate, complete, and supported by documentation in the patient's medical record.

1 Patient and Insurance Information

- Patient's full name, gender, address, and date of birth
- Patient's pharmacy benefit plan information (plan name and member ID or patient's ID card)

2 Prior Treatment History

Documentation of other treatments tried and failed

Over-the-counter products such as artificial tears and prescription medications:

- Product name and formulation type (gel, ointment, or solution)
- Dose and frequency used
- Dates used and duration of treatment
- Patient's response to treatment

3 Diagnostic Information

Provide name of product along with documentation that validates the patient's need for the medication

Supporting diagnosis information specific to the medication requested

- ICD-10 diagnosis code(s)
- Date of diagnosis
- Diagnostic testing with results

Examples may include^{1,2}:

- Schirmer's Test Score
- Tear film break-up time (TBUT)
- Ocular surface staining
- Slit-lamp examination
- Blink rate
- Matrix metalloproteinase-9 (MMP-9)
- Corneal sensitivity

4 Clinical Rationale

Supporting information specific to the medication being requested

Examples may include:

- Dosing schedule
- Mechanism of action
- Route of administration (nasal spray, eye drops)

Relevant patient history

Examples may include:

- Changes in diagnosis or condition that justify the requested medication
- Patient adherence and clinical results to prior treatments
- Pertinent comorbid conditions
 - Inability to self-administer eye drops due to a neurological condition such as tremor disorder, Parkinson's Disease, etc.
 - Inability to tolerate eye drops due to a condition such as ocular surface damage, other eye condition, etc.
- Functional impact of dry eye disease on work and home life (e.g., ability to drive, ability to wear contact lenses, be in sunlight, reduced visual acuity, visual disturbance, screen use, reading, etc.)
- Results of eye dryness questionnaire (symptoms, frequency, severity), including date patient completed



IMPORTANT INFORMATION

- If a PA is required by the insurance plan, you'll receive a notification with a unique key code to complete the PA request and submit it to the health plan
- The information submitted to the health plan must be substantiated in the patient's medical record and available upon request from the health plan



QUICK TIPS

- Make a copy of the patient's pharmacy insurance card to keep with their patient profile
- Be thorough when collecting and documenting patient's prior treatment history
 - Comprehensive documentation can create a more efficient PA process and can be helpful for completing other insurance coverage forms



DID YOU KNOW:

Formulary Exceptions:

A **Formulary Exception** request may be submitted to the patient's insurance plan to request coverage of a non-formulary drug. Plan-specific Formulary Exception forms are available on the plan's website or in the plan's provider portal.

Many insurance plans accept a PA to request coverage of non-formulary drugs. When a PA is accepted, a Formulary Exception request will *not* be needed.

Tiering Exceptions:

A **Tier Exception** request may be submitted to the patient's insurance plan to obtain a non-preferred drug at the lower cost sharing terms applicable to drugs in a preferred tier.

Plan-specific Tier Exception forms are available on the plan's website or in the plan's provider portal. Tier Exceptions for CVS (e.g., Silverscript and Aetna) and Well Care plans may also be submitted using CoverMyMeds.

ICD-10=International Classification of Diseases, Tenth Revision.

Indication

Tyrvaya[®] (varenicline solution) nasal spray is indicated for the treatment of the signs and symptoms of dry eye disease.

Important Safety Information

The most common adverse reaction reported in 82% of patients was sneezing. Events that were reported in 5-16% of patients were cough, throat irritation, and instillation-site (nose) irritation.

Please click here for full Prescribing Information.



GLOBAL links to: <https://www.tyrvaya-pro.com/files/prescribing-information.pdf>

Common Appeal Requirements

This checklist contains common Prior Authorization requirements seen in practice and may not consist of everything required by an insurance plan. Thus, the content provided in this guide is for informational purposes and is not intended as legal advice or to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure that Tyrvaya claims are accurate, complete, and supported by documentation in the patient's medical record.

1 If the health plan has denied coverage for Tyrvaya:

Review the denial letter sent to you by the health plan

- If you don't have the letter, you may contact the insurance plan to obtain a copy of the denial notification

2 If appropriate, write a letter of appeal to support your request for reconsideration

Customize the letter based on the reason for denial and the patient's clinical needs, clearly documenting:

- The letter is to appeal the denial and request reconsideration for coverage
- The plan's reason for denial
- The case identification number if provided by the plan

To further substantiate your request for coverage, consider providing the patient's clinical and treatment history, such as:

- Diagnosis, date of diagnosis, and results of diagnostic assessment
- Treatments and medications the patient has tried and failed, including dates tried and response to treatment (be as specific as possible, including the brand names of other therapies, including artificial tears)
- Any limitations the patient has with regard to prior treatments or formulary alternatives (e.g., inability to self-administer eye drops or intolerance to eye drops)
- How the disease is impacting the patient's QoL and/or ability to work

Consider attaching supporting documentation for your request, such as:

- Chart documentation specific to the patient's clinical and treatment history
- Patient's response to a Tyrvaya trial when using a sample supply, including duration of the trial
- Tyrvaya Prescribing Information
- Peer reviewed studies

3 Submission and Follow-Up

Confirm how the appeal should be sent to the plan (by fax or mail)

- Appeal requirements can be found in the denial notification from the plan; you may also call the plan directly or reference the plan's provider portal to confirm requirements
 - Provide a prescriber and patient signature when required by the plan
 - Confirm all documentation provided is accurate and complete
 - Follow up with the health plan to confirm receipt of your appeal and to check determination status
- eAppeal may be available through CoverMyMeds or the plan's provider portal
- Expedited review of the appeal may be available upon request



COMMON REASONS FOR COVERAGE DENIAL:

Current and Prior Treatment History

- Patient's trial and failure of formulary alternatives, including clinical response
- Combination/concomitant use of multiple dry eye therapies

Diagnostic Documentation

- Diagnostic testing which confirms dry eye disease
 - Include assessment results with findings of abnormality and/or severity of disease
- Valid ICD-10 coding must include the full 7 characters to provide the greatest level of detail to describe the patient diagnosis
- Patient must be diagnosed with a disease consistent with the FDA-approved indication for the medication

Visit www.tyrvaya-pro.com/resources to view a sample letter of medical necessity for appeal



HELPFUL TIPS

- Notify the pharmacy when you receive the appeal determination. If coverage is approved, the pharmacy can reprocess the prescription
- Since appeal determinations can take up to 60 days, it is very important to submit the appeal promptly

FDA=Food and Drug Administration; QoL=quality of life.

Please see page 3 for information on Tyrvaya's NDC number and ICD-10 codes for dry eye diagnosis.

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Please click [here](#) for full Prescribing Information.

NDC and ICD-10 Codes

NDC Code³

Product	NDC Code
Tyrvaya® nasal spray	73521-030-02

ICD-10 Codes⁴

Example ICD-10 Codes for Dry Eye Diagnosis

Description	ICD-10	Right	Left	Bilateral	Unspecified
Dry eye syndrome: tear film insufficiency, nitric oxide synthase (NOS) (lacrima gland)	—	H04.121	H04.122	H04.123	H04.129
Keratoconjunctivitis sicca, not specified as Sjögren's syndrome	—	H16.221	H16.222	H16.223	H16.229

These diagnosis code examples are provided for general educational and informational purposes only and are not intended to be directive, a guarantee of coverage, or a substitute for independent clinical decision making.

This information is current as of July 2024 and is subject to change. Payer coding requirements vary and can frequently change, so please check with each payer as to payer-specific requirements. You are solely responsible for determining the appropriate codes and for any action you take in billing. The information provided here is not intended to be definitive or exhaustive, and is not intended to replace the guidance of a qualified professional advisor.

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

Prescribing Tyrvaya to PhilRx allows your patients to take advantage of TEAMTyrvaya, which offers benefits verification assistance, coverage support, and affordability options.



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References: **1.** Akpek EK et al. *Ophthalmology*. 2019;126(1):286-334. **2.** Zeev MS et al. *Clin Ophthalmol*. 2014;8:581-590. **3.** Tyrvaya. Prescribing Information. Oyster Point Pharma; 2024. **4.** CMS.gov. 2024 ICD-10-CM. Accessed July 26, 2024. <https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm>.