



Healthcare Professional

TEPEZZA Payor Access Guide

A resource to help you navigate payor access

INDICATION

TEPEZZA is indicated for the treatment of Thyroid Eye Disease.

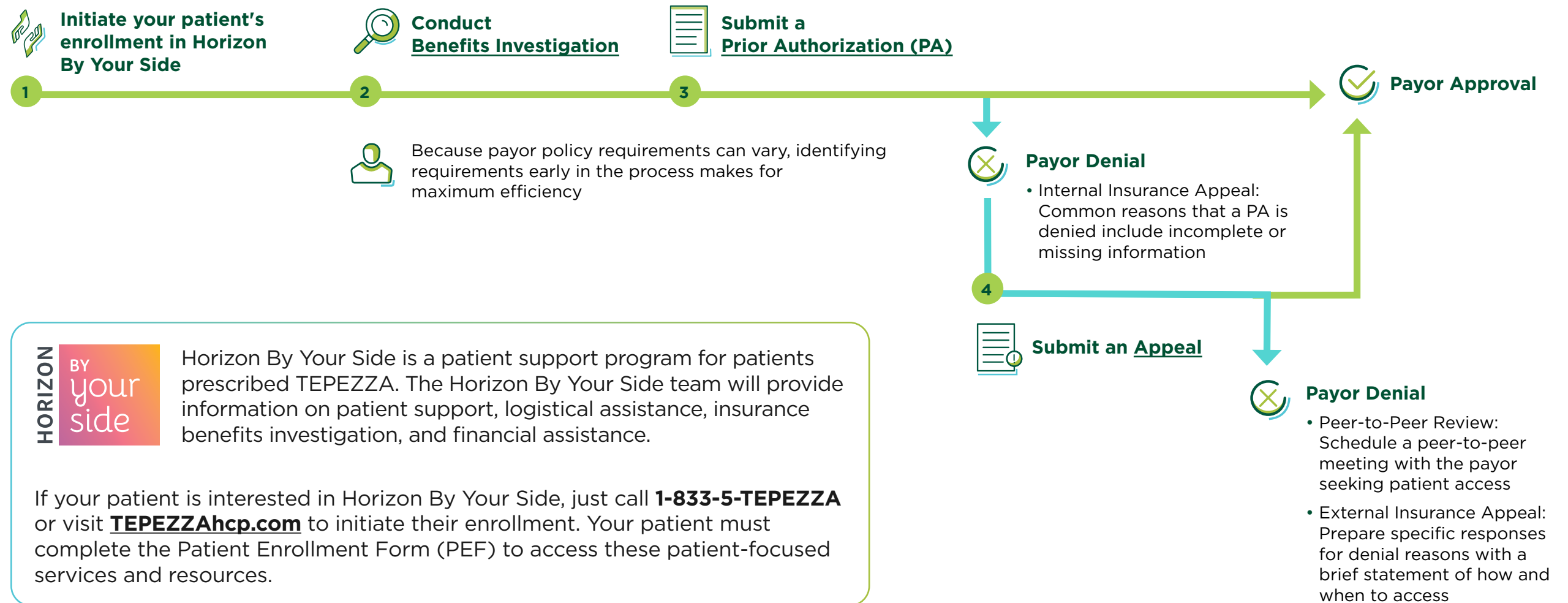
Please see Important Safety Information on the last page and see [Full Prescribing Information](#).

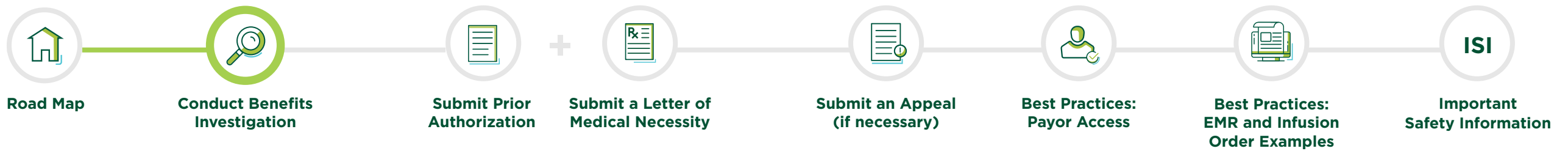

TEPEZZA[®]
teprotumumab-trbw



Horizon offers resources to support patients at every step of the access process

Many treatments require initial action from the HCP and office staff for patients to get access. Click on the underlined areas of the access map, or the navigation above, to find more detailed information and resources available at each step of the process.





Conduct benefits investigation (BI)

To identify coverage and reimbursement for a patient, a BI must be completed. Requirements for covering TEPEZZA will vary between health plans.

A BI may help answer questions about:



Coverage

TEPEZZA coverage

- Is TEPEZZA covered?
- If so, is it covered under the medical benefit or pharmacy benefit?

Prior authorization (PA)

- Will a PA be required for treatment with TEPEZZA?
- What is the process for obtaining a PA?
- What information will be required, and how long will the process take?
- How long will the PA remain valid?

Benefits coordination

- Does the patient have any other supplemental insurance benefits that would require coordination?
- Which benefit is primary? Which is secondary?



Reimbursement

Coding and claims submission

- What are the specific coding and claims submission requirements for reporting TEPEZZA in this patient's plan?
- What codes should be noted on the claim form?
- What type of documentation is required?

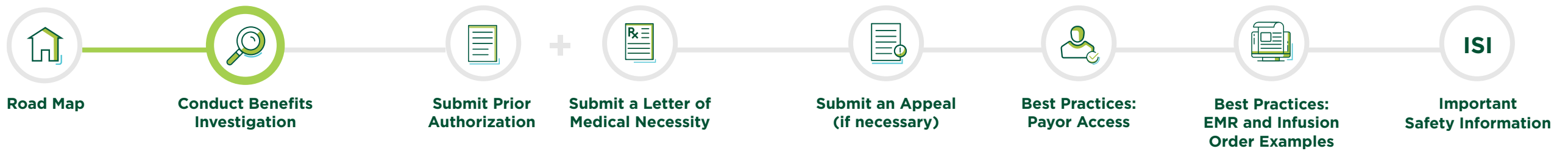
Reimbursement for TEPEZZA

- What is the reimbursement amount provided for TEPEZZA (drug and services)?



The **Billing and Coding Guide** is available to download for more information on coding, billing, and reimbursement

Determine what insurance your patient has, as the process and requirements differ between various health plans



Conduct benefits investigation (BI) (cont'd)

To identify coverage and reimbursement for a patient, a BI must be completed. Requirements for covering TEPEZZA will vary between health plans.

A BI may help answer questions about:



Patient out-of-pocket costs

Patient financial responsibility

- What is the annual deductible amount the patient must meet?
 - Has this amount been met? What is the amount left?
- What is the patient's co-payment or coinsurance for TEPEZZA?
- Is there a maximum out-of-pocket amount the patient must meet?
 - Has this amount been met? What is the amount left?
- Does the patient's plan contain an annual or lifetime maximum?
 - Has this amount been met? What is the amount left?

A BI can help communications between a prescriber and a payor by:

- Clarifying the medical necessity for a patient to have TEPEZZA and avoiding payor denial
 - TEPEZZA is medically appropriate
 - Prescribing TEPEZZA is in accordance with generally accepted standards of medical practice

A BI can identify your patient's financial options



Patients with commercial insurance may qualify for a \$0 co-pay for both the cost of the medication and the IV infusion through our commercial co-pay assistance program.*



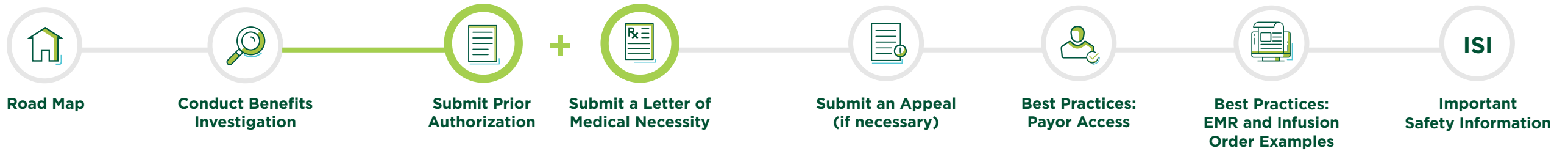
Patients with government insurance, such as Medicare, may be eligible for independent foundation support.†



For uninsured patients, contact Horizon By Your Side at 1-833-5-TEPEZZA (TEPEZZA medication only).

*Terms and Conditions: Offer cannot be combined with any other rebate or coupon, free trial, or similar offer for the specified prescription. Not valid for prescriptions reimbursed in whole or in part by Medicaid, Medicare, VA, DOD, TRICARE, or other federal or state programs (including state prescription drug programs). Offer good only in the United States at participating specialty pharmacies or sites of care. Offer not valid where otherwise prohibited by law, for example by applicable state law prohibiting co-pay cards. Horizon Therapeutics reserves the right to rescind, revoke, or amend offer without notice. The selling, purchasing, trading, or counterfeiting of this card is prohibited by law. This card is not insurance and is not intended to substitute for insurance. Participating pharmacy or healthcare provider: by using this co-pay program, you acknowledge and confirm that the patient is not insured by a federal healthcare program and meets the eligibility criteria set forth in the terms and conditions. Patients: by enrolling in this co-pay program, you acknowledge and confirm that you meet the eligibility requirements set forth in the terms and conditions. Patients must be 18 or older.

†Please note that independent foundations establish, administer, and implement the funds, which are separate and apart from Horizon.



Submit a prior authorization (PA)

The PA process allows the payor to review the reason for the requested therapy and to determine medical appropriateness. Clinical documentation requirements will vary between health plans.



A payor policy for a PA may include the following common criteria:

Clinical Activity Score (CAS) codes and severity to fully describe a patient's condition and associated manifestations

- What is the patient's Thyroid Eye Disease (TED) diagnosis presenting on examination?¹
 - Spontaneous orbital pain
 - Gaze-evoked orbital pain
 - Eyelid swelling that is considered to be due to Acute TED
 - Eyelid erythema
 - Conjunctival redness that is considered to be due to Acute TED
 - Chemosis
 - Inflammation of caruncle or plica
 - **Increase of >2 mm in proptosis**
 - **Decrease in uniocular excursion in any one direction of >8°**
 - **Decrease of acuity equivalent to 1 Snellen line**

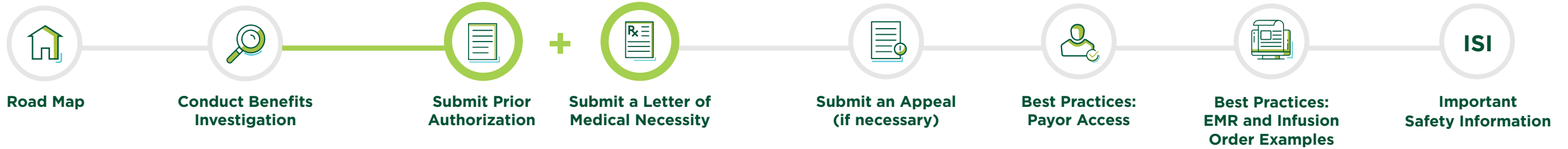
See detailed CAS descriptions and codes in the Appendix of the [Billing and Coding Guide](#)



Your office may need to coordinate with the referring physician (eg, endocrinologist, general ophthalmologist) to gather baseline clinical requirements needed to complete the PA

Documenting a patient's CAS via electronic medical record may help streamline the PA process for everyone involved





Submit a prior authorization (PA) (cont'd)

Writing a letter of medical necessity (LOMN)

A best practice for effectively communicating clinical rationale for TEPEZZA (or prior authorization) is to write an LOMN that addresses a payor's TEPEZZA medical policy. A patient-specific LOMN explains the physician's rationale and clinical decision-making in choosing TEPEZZA.

[Office letterhead]

[Date]

[Contact name of medical director or other payor representative]
[Contact title]
[Name of health insurance company]
[Address]

Re: Letter of Medical Necessity for [HCPCS Code] [Drug name, billing unit]
Patient: [Patient Name]
Group/Policy Number: [Number]
Date(s) of Service: [Dates]
Diagnosis: [Code and description]

Dear [Insert contact name or department],

I am writing on behalf of my patient, [PATIENT NAME], to document medical necessity for treatment with TEPEZZA® (teprotumumab-trbw). This patient will be treated for Thyroid Eye Disease (TED) with TEPEZZA, which is indicated for the treatment of TED.¹ This letter serves to document that [PATIENT] needs TEPEZZA and that TEPEZZA is medically necessary for them as administered. On behalf of the patient, I am requesting approval for use and subsequent payment for treatment.

1 **Medical History and Diagnosis**
[PATIENT NAME] is [a/an] [AGE]-year-old [MALE/FEMALE] diagnosed with Thyroid Eye Disease (TED). [PATIENT NAME] has been in my care since [DATE]. As a result of TED, my patient [ENTER BRIEF DESCRIPTION OF PATIENT HISTORY]. Additionally, [PATIENT NAME] has tried [PREVIOUS TREATMENTS] and [OUTCOMES]. The attached medical records document [PATIENT NAME]'s clinical condition and the medical necessity for treatments with TEPEZZA.

Based on the above facts, I am confident that you will agree that TEPEZZA is indicated and medically necessary for this patient. The plan of treatment is to start the patient on TEPEZZA. Administration of TEPEZZA 10 mg/kg is planned on [DATE] and will be continued approximately every 3 weeks at 20 mg/kg for a total of 8 infusions.¹

2 Please consider coverage of TEPEZZA on [PATIENT NAME]'s behalf and approve use and subsequent payment for TEPEZZA as planned. Please refer to the enclosed Prescribing Information for TEPEZZA. If you have any further questions, please call me at [PHYSICIAN TELEPHONE NUMBER].

Thank you for your prompt attention to this matter.

Sincerely,

3 [PHYSICIAN NAME], [DEGREE INITIALS]
[PROVIDER IDENTIFICATION NUMBER]

The following is a template LOMN for TEPEZZA that can be customized based on your patient's medical history and demographic information. Some payors may have specific forms that must be completed in order to document medical necessity

- 1 Provide relevant medical information and attach patient's medical records and/or supporting documents for payors to review
- 2 Download a copy of the [Full Prescribing Information](#)
- 3 Check with the payor to identify specific documentation that needs to be submitted with an LOMN



The [LOMN template](#) is available for download




It may be beneficial to submit an LOMN, even if it is not explicitly asked for, to avoid delay



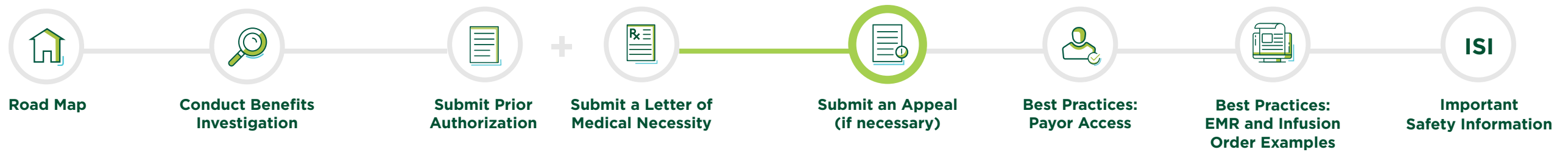
Submit a prior authorization (PA) (cont'd)

The PA process allows the payor to review the reason for the requested therapy and to determine medical appropriateness. Clinical documentation requirements will vary between health plans.

When submitting the PA, be sure to: _____

-  Thoroughly complete every section of the PA form; review it carefully, as each payor may have unique requirements
-  Provide supporting documentation, including but not limited to:
 - Medical records
 - Chart notes
 - A letter of medical necessity
 - Publications and references
-  Inquire about how long the process will take once necessary documents have been submitted





Writing an appeal letter (should a denial occur)



When writing an appeal letter, ensure you address the specific details of the denial reason(s)

Supplemental documentation may include:

- A copy of your patient's medical records
- Recent photo(s) of affected eye(s)
- Summary of your recommendation at end of letter
- Letter of medical necessity (LOMN)
- Supporting scientific publications/journal articles

Make sure you:

- Match the exact language from the denial letter. It is imperative to address the specifics of the denial
- Call out if you are including an LOMN, or any other attachments, along with your appeal letter
- Schedule an additional patient appointment, if needed, to confirm clinical presentation

Now that you have submitted the letter, along with any supporting documentation, the payor will review and decide on coverage approximately within:



for urgent care



for non-urgent care



for services already provided

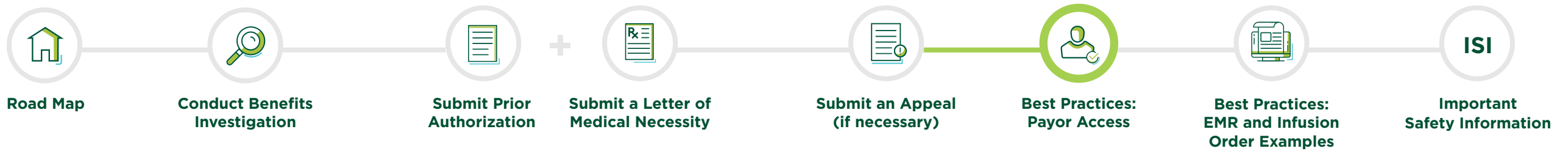
To initiate an expedited appeal, contact your patient's healthcare insurance provider.

If an LOMN was not submitted with your PA, consider including it with the appeal letter

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Providers are encouraged to contact third-party payors for specific information about their coverage policies. For more information, please call a Reimbursement Access Specialist at 1-833-583-7399.

For Medicare beneficiaries, there are specific requirements that need to be met for the healthcare provider to be considered a legal representative of the patient in an appeal. For additional information, please visit <https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals> for Part B appeals, or <https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf> for Part D appeals.

Please see Important Safety Information on the last page and see Full Prescribing Information.



Payor access best practices: open communication between provider, payor, and site of care (SOC)



Having a system, such as an electronic medical record (EMR), can make the journey to reimbursement more efficient and accurate

- [Click here](#) to see examples



Recognize that policy requirements may vary considerably from payor to payor

- Identifying each payor's policy early is critical for smooth transactions between provider, payor, and patient
- Knowing payor policies up front provides clarity for patients on out-of-pocket expenses



Provide your infusion SOC with the patient's medical records, chart notes, and any necessary documentation to assist with fulfilling payor requirements. Information may include:

- Prescription/infusion order
- Referral form
- Insurance information
- Diagnosis
- Prior authorization
- Medical necessity codes and notes
- Detailed protocol outlining dosage/concentration, quantity, route, duration, and other therapeutic medications that were in place pre-infusion and that need to be administered during and after infusion
- Progress notes with care plans in place
- Coordination with SOC to determine if clinical care coordination is required
- Lab requisitions as needed



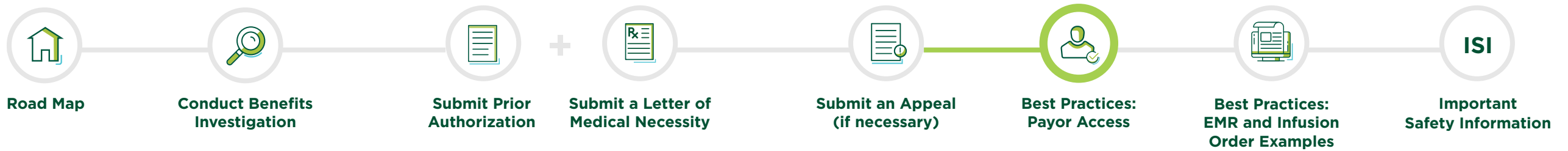
Establish process to capture thorough documentation of Clinical Activity Score (CAS) in chart notes

- CAS-related ICD-10-CM diagnostic codes may be necessary to fully describe the patient's condition and associated manifestations
- Keeping careful CAS descriptions will help with creating prior authorizations and letters of medical necessity. It is important to include CAS within your clinical documentation
- It may be necessary to coordinate with the referring HCP (eg, endocrinologist, general ophthalmologist) for baseline CAS



Identify one staff member to be in charge of all infusion claims and reimbursement matters

- Having a single person in charge of the details of payor access can help ensure that all documentation is complete and filed in one place
- Coordinating closely with the SOC to ensure all necessary documentation is accurate, thorough, and complete will help facilitate filing claims and receiving reimbursements



The importance of Clinical Activity Score (CAS) in your patient records

CAS information is key for supporting and facilitating the prior authorization process. It is a tool designed to evaluate inflammatory signs and symptoms that are characteristic of Thyroid Eye Disease (TED).¹

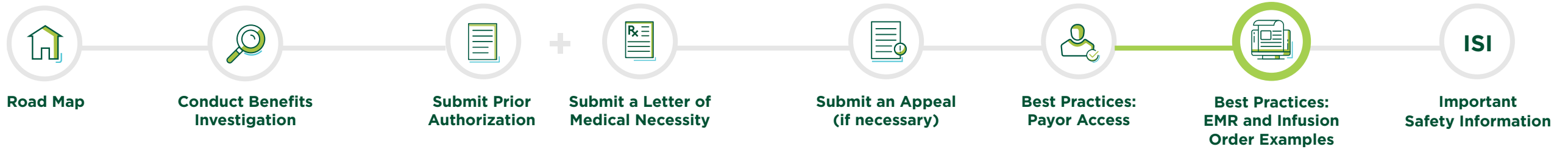
When determining CAS, 1 point is given for each sign or symptom.* At baseline assessment, a CAS ≥ 3 indicates Acute TED. For ongoing monitoring, all 10 descriptors should be considered.^{1,2}

1. Spontaneous orbital pain
2. Gaze-evoked orbital pain
3. Eyelid swelling that is considered to be due to Acute TED
4. Eyelid erythema
5. Conjunctival redness that is considered to be due to Acute TED
6. Chemosis
7. Inflammation of caruncle or plica
- 8. Increase of >2 mm in proptosis**
- 9. Decrease in uniocular excursion in any one direction of >8°**
- 10. Decrease of acuity equivalent to 1 Snellen line**

The table on the right shows the commonly used CAS-related and other relevant ICD-10-CM diagnostic codes that are used to meet prior authorization criteria.

ICD-10-CM Codes ⁵	Description
H02.531-H02.539	Eyelid retraction
H02.841-H02.849	Edema of eyelid
H04.121-H04.129	Dry eye syndrome of lacrimal glands
H05.241-H05.249	Constant exophthalmos
H05.251-H05.259	Intermittent exophthalmos
H10.421-H10.429	Simple chronic conjunctivitis
H11.131-H11.139	Conjunctival pigmentations
H11.141-H11.149	Conjunctival xerosis
H11.411-H11.419	Vascular abnormalities of conjunctiva
H11.421-H11.429	Conjunctival edema
H11.431-H11.439	Conjunctival hyperemia
H16.211-H16.219	Exposure keratoconjunctivitis
H46.8	Other optic neuritis
H47.011-H47.019	Ischemic optic neuropathy
H47.091-H47.099	Other disorders of optic nerve
H50.21-H50.22	Vertical strabismus
H50.69	Other mechanical strabismus
H53.2	Diplopia
H53.451-H53.459	Other localized visual field defect
H57.10-H57.13	Ocular pain

*While CAS is a useful tool, some patients may not present with these characteristic signs of inflammation, and additional evaluation may be required to determine Acute TED. At initial visit, a score of 3 or more out of 7 is considered Acute TED; at follow-up, a 10-point CAS is used, and a score of 4 or more is considered Acute TED.^{1,3,4}



Electronic medical record (EMR) examples

Utilizing EMRs starting with the first appointment can help ensure thorough documentation. EMRs are not always automatically connected from provider to SOC. To ensure an SOC receives Clinical Activity Score (CAS) and other documentation needed for the prior authorization process, have your office take the extra step of sending a patient’s chart notes to the SOC.

EMRs can vary by practice, but they will usually include a detailed diagnosis, treatment plan options, and a description of current symptoms and signs based on CAS.

Below are detailed examples of what an EMR smart template might include.

ELECTRONIC MEDICAL RECORD (EMR)

XX/XX/XXXX

Patient History

- Weight: XXX

- Hyperglycemia: XXX

- Inflammatory bowel disease: XXX

- Pregnancy/birth control: XXX

- XXX mild/moderate/severe, active/inactive, stable/progressing Thyroid Eye Disease

- Thyroid disease diagnosed: XXX

- XXX +FH

- Eye symptoms beginning: XXX, reports XXX

- Smoking status:

- HVF 24-2:

- External photos: 08/27/20

- Exam consistent with XXX

- Last thyroid labs (XXX):

Plan:

We discussed that Thyroid Eye Disease is an autoimmune process that can have an inflammatory course of approximately 3 years in duration. Signs and symptoms that may occur during the inflammatory course was discussed in detail.

In addition, some patients may experience inflammatory activity or flares at any point in the disease course.

Clinical Presentation

Pain

1. Painful, oppressive feeling on or behind the globe during last two weeks

2. Pain on attempted up, side, or down gaze during the last 4 weeks

Redness

3. Redness of the eyelids

4. Diffuse redness of conjunctiva covering at least one quadrant

5. Swelling of eyelids

Redness (cont'd)

6. Chemosis

7. Swollen caruncle

Impaired Function

8. Increase of >2 mm in proptosis

9. Decrease in uniocular excursion in any one direction of >8°

10. Decrease of acuity equivalent to 1 Snellen line

TOTAL SCORE:

XXX

ELECTRONIC MEDICAL RECORD (EMR)

XX/XX/XXXX

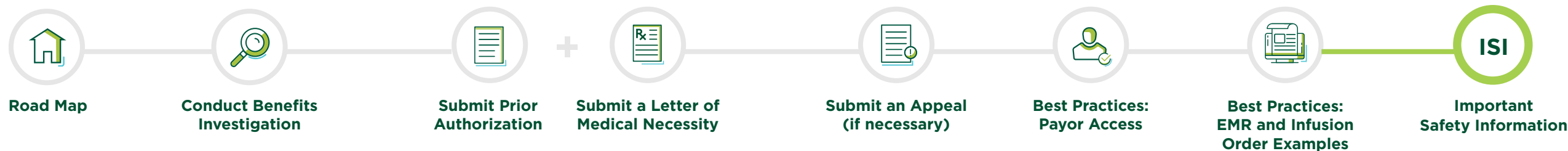
Notes

This patient has moderate-to-severe Thyroid Eye Disease.

I discussed the use of teprotumumab for the treatment of Thyroid Eye Disease. We discussed the common side effects including muscle cramping, nausea, diarrhea, and headache. Less common side effects including change in blood sugar, alopecia, and hearing changes were also discussed with the patient.

After a detailed conversation, the patient and I have opted to proceed with initiation of teprotumumab treatment.

Clinical Activity Score (CAS):	XXX
Eyelid retraction (Y/N): (see MRD1 measurements in exam)	XXX
Diplopia? (Y/N):	XXX
Gorman Diplopia Grade (0-3):	XXX
Proptosis? (Y/N): (see Hertel measurements in exam)	XXX
Is Thyroid Eye Disease active and progressive? (Y/N):	XXX
Is patient followed by endocrinology or primary care physician and working to optimize thyroid function? (Y/N):	XXX
Prior corticosteroids?:	XXX



INDICATION

TEPEZZA is indicated for the treatment of Thyroid Eye Disease.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion Reactions: TEPEZZA may cause infusion reactions. Infusion reactions have been reported in approximately 4% of patients treated with TEPEZZA. Reported infusion reactions have usually been mild or moderate in severity. Signs and symptoms may include transient increases in blood pressure, feeling hot, tachycardia, dyspnea, headache, and muscular pain. Infusion reactions may occur during an infusion or within 1.5 hours after an infusion. In patients who experience an infusion reaction, consideration should be given to premedicating with an antihistamine, antipyretic, or corticosteroid and/or administering all subsequent infusions at a slower infusion rate.

Preexisting Inflammatory Bowel Disease: TEPEZZA may cause an exacerbation of preexisting inflammatory bowel disease (IBD). Monitor patients with IBD for flare of disease. If IBD exacerbation is suspected, consider discontinuation of TEPEZZA.

Hyperglycemia: Increased blood glucose or hyperglycemia may occur in patients treated with TEPEZZA. In clinical trials, 10% of patients (two-thirds of whom had preexisting diabetes or impaired glucose tolerance) experienced hyperglycemia. Hyperglycemic events should be controlled with medications for glycemic control, if necessary. Assess patients for elevated blood glucose and symptoms of hyperglycemia prior to infusion and continue to monitor while on treatment with TEPEZZA. Ensure patients with hyperglycemia or preexisting diabetes are under appropriate glycemic control before and while receiving TEPEZZA.

ADVERSE REACTIONS

The most common adverse reactions (incidence $\geq 5\%$ and greater than placebo) are muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache, dry skin, weight decreased, nail disorders, and menstrual disorders.

Please see [Full Prescribing Information](#) or visit [TEPEZZAhcp.com](https://tepezzahcp.com) for more information.

References: **1.** Barrio-Barrio J, Sabater AL, Bonet-Farriol E, Velázquez-Villoria Á, Galofré JC. Graves' ophthalmopathy: VISA versus EUGOGO classification, assessment, and management. *J Ophthalmol*. 2015. doi:10.1155/2015/249125 **2.** Bartalena L, Baldeschi L, Boboridis K, et al; European Group on Graves' Orbitopathy (EUGOGO). The 2016 European Thyroid Association/European Group on Graves' Orbitopathy guidelines for the management of Graves' orbitopathy. *Eur Thyroid J*. 2016;5(1):9-26. **3.** Mourits MP, Prummel MF, Wiersinga WM, Koornneef L. Clinical activity score as a guide in the management of patients with Graves' ophthalmopathy. *Clin Endocrinol (Oxf)*. 1997;47(5):9-14. **4.** Laurberg P, Berman DC, Pedersen IB, Andersen S, Carlé A. Double vision is a major manifestation in moderate to severe Graves' orbitopathy, but it correlates negatively with inflammatory signs and proptosis. *J Clin Endocrinol Metab*. 2015;100(5):2098-2105. **5.** Centers for Disease Control and Prevention. ICD-10-CM Tabular List of Diseases and Injuries. Accessed January 27, 2022. <https://www.cdc.gov/nchs/icd/icd-10-cm.htm>



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