AVEO ONCOLOGY
an LG Chem company

FOTIVDA®
(tivozanib) capsules

PRIOR AUTHORIZATION AND APPEALS TOOLKIT FOR FOTIVDA® (tivozanib)

A guide to help navigate prior authorizations and appeals that may be required to obtain insurance coverage for FOTIVDA

The information contained in this toolkit is provided for informational purposes. Providers are responsible for the accuracy and completeness of all information and materials submitted requesting coverage for an individual patient. Please refer to the full Prescribing Information for FOTIVDA® (tivozanib), when determining whether the therapy is clinically appropriate for your patient.

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GETTING YOUR PATIENT STARTED:

Health plan coverage will vary based on the type of plan and their individual coverage policy for certain drugs. Use this guide to review the coverage process and apply best practices for navigating the reimbursement process. You can click the tabs to jump to specific sections of this guide.

1. Submit your patient's prescription

FOTIVDA® (tivozanib) can be submitted to one of our limited distribution specialty pharmacies or to your own in-office dispensing pharmacy. For additional support and resources for your patient, you can complete the FOTIVDA enrollment form to enroll your patient in the AVEO ACE Patient Support Program.

2. Check your patient's health benefits

Determine the specific coverage criteria for your patient's health plan. The specialty pharmacy can usually submit an electronic claim to the plan to receive coverage details or call the pharmacy benefits manager. If you need additional help with this, reach out to AVEO ACE Patient Support.

3. Submit a Prior Authorization (PA) to your patient's plan

Most specialty drugs require a prior authorization to ensure the prescribed treatment is medically appropriate and meets the plan's coverage criteria. PA requirements may vary by payer, so be sure to check your patient's health plan for specific requirements before submitting the request. You can obtain the appropriate PA form from your patient's insurance provider, specialty pharmacy, or AVEO ACE.

4. Medical Exceptions

A formulary exception is another type of coverage request that is used when a medication is not included on the plan's formulary, or is excluded (blocked) from the formulary. Exceptions may also be requested for clinical reasons, such as when a patient cannot tolerate formulary alternatives, or when a waiver is needed for other restrictions, such as tier assignments, to lower the patient's out-of-pocket costs for a non-preferred drug.

5. If the PA is Denied, Prepare and Submit an Appeal

If the PA or Exception Request has been denied, the patient's health plan will provide specific instructions on how to submit an appeal. It's important to review the plan's appeal guidelines, clearly address the denial reasons in your written explanation, and submit the appeal with appropriate documentation as soon as possible.

6. Once Coverage is Approved, Schedule Delivery

If the health plan approves the PA or Appeal, the specialty pharmacy or your in-office pharmacy will submit the claim and coordinate delivery with the patient. If the denial is upheld, AVEO ACE can check if your patient might be eligible to receive FOTIVDA at no cost.

PRIOR AUTHORIZATION CHECKLIST

The following information is generally required by most plans; please check with the payer for specific requirements. AVEO ACE can also assist in furnishing information about accessing FOTIVDA® (tivozanib) and provide support throughout your patient's treatment journey.

STEP 1: PATIENT INFORMATION

- ☐ Patient Name
- ☐ Date of Birth
- ☐ Insurance Carrier
- ☐ Insurance ID
- ☐ Insurance Group Number
- ☐ Case ID Number (if applicable)

STEP 2: CLINICAL RATIONALE

- ☐ Patient's diagnosis and FOTIVDA indication
- ☐ Severity of patient's condition
- ☐ Summary of patient's treatments, duration of treatments, responses, reason for discontinuation, and recent symptoms/conditions. Include coding information for prior treatments/services (if available/applicable).
- ☐ Clinical rationale for FOTIVDA, including clinical trial data supporting FDA approval, administration, and dosing information.

STEP 3: PRESCRIBER INFORMATION

- ☐ Name
- ☐ National Provider Identifier (NPI) Number
- ☐ Specialty
- ☐ Contact Information

PRIOR AUTHORIZATION (CONT'D)

STEP 4: SUPPORTING FORMS AND DOCUMENTS

- ☐ Letter of Medical Necessity (LMN) from the healthcare provider that explains why the FOTIVDA® (tivozanib) treatment is necessary.
- ☐ Formal letter appealing the denial. Some plans will have a specific appeal form that must be included.
- ☐ A copy of the prior authorization denial letter from the plan.
- ☐ An Assignment of Benefits (AOB) form signed by the patient is required by some plans and may delay the medical review process if not included.
- ☐ Relevant documentation regarding the treatment decision: chart notes, previously tried treatments, labs, FOTIVDA package insert.
- ☐ Include published clinical literature or journals to support FOTIVDA treatment for the patient's diagnosis.

BEST PRACTICES TO SUBMIT AN APPEAL

A Letter of Appeal is typically submitted when a claim has been denied. To initiate the process of submitting an appeal, complete the following steps:

STEP 1: VERIFICATION OF WHETHER A DENIAL HAS OCCURRED

- ☐ Review the denial letter from the health plan to determine the specific reason for the FOTIVDA® (tivozanib) denial. If you did not receive the PA denial letter be sure to contact the health plan and request a copy.

Common denial reasons include:

- *Not medically necessary – based on diagnosis and relevant treatment history the plan determined the prescribed therapy is not medically necessary.*
- *Not covered, patient must try formulary alternatives – for this condition or diagnosis, the plan's coverage policy will only approve preferred formulary alternatives.*
- *Formulary exclusion – the medication requested or the therapy class is excluded from the plan's formulary for coverage.*
- *Incomplete or missing information – the information submitted was not sufficient for the plan to make a determination, or the information was submitted incorrectly.*

STEP 2: PROCESS FOR SUBMITTING AN APPEAL

- ☐ Check with the health plan for their specific instructions on how to submit an appeal.
  - *Some health plans may require a specific appeal form or Assignment of Benefits (AOB) form to be signed by the patient before they will accept the appeal for review. If this form is missing it may delay the appeal decision.*

STEP 3: SUBMITTING THE LETTER OF APPEAL

- ☐ Submit a Letter of Appeal including any relevant treatment information, and be sure to include additional information that was not presented in the PA submission.
  - *It's important to address the specific denial reason in the appeal submission to further support the rationale for the treatment.*
- ☐ Include published medical literature or peer to peer journals that support the treatment for the patient's diagnosis.
  - *See Prior Authorization Checklist on page 4*

STEP 4: TRACKING AND FOLLOW-UP

- ☐ You can ask for an expedited review when necessary for the patient to start treatment quickly, track all reference numbers, and be sure to follow-up with the plan for a decision.

SAMPLE LETTER OF APPEAL

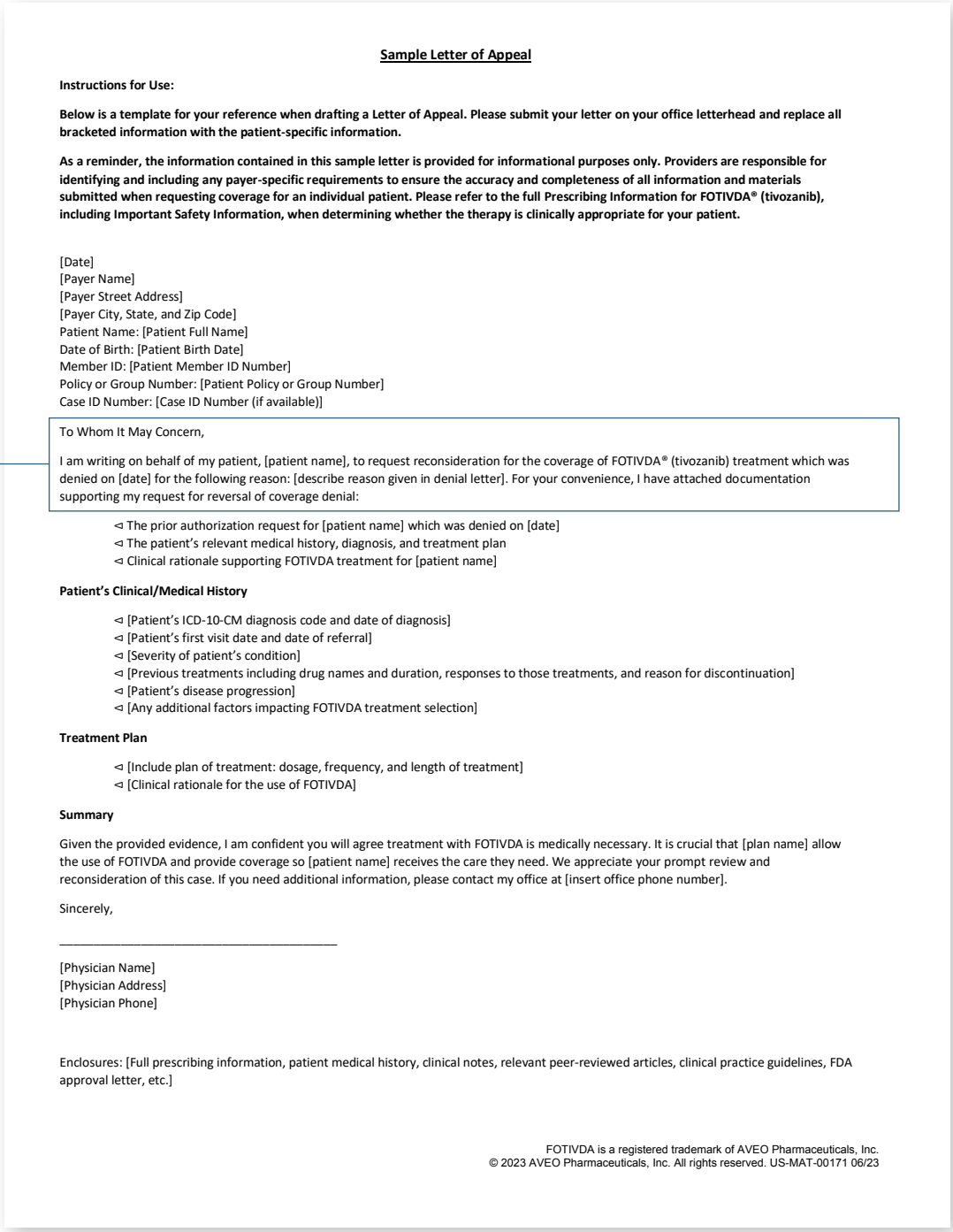
Below is a template for your reference when drafting a Letter of Appeal. The information contained in this sample letter is provided for informational purposes only.

If this appeal has been previously been denied, consider including:

This is a formulary exception appeal. I have included a copy of the original denial letter and medical notes in response to the denial.

For previously denied appeals, include the following:

- A copy of the denial letter
- Medical notes, written by the prescribing physician, in response to the denial letter



Sample Letter of Appeal

Instructions for Use:

Below is a template for your reference when drafting a Letter of Appeal. Please submit your letter on your office letterhead and replace all bracketed information with the patient-specific information.

As a reminder, the information contained in this sample letter is provided for informational purposes only. Providers are responsible for identifying and including any payer-specific requirements to ensure the accuracy and completeness of all information and materials submitted when requesting coverage for an individual patient. Please refer to the full Prescribing Information for FOTIVDA® (tivozanib), including Important Safety Information, when determining whether the therapy is clinically appropriate for your patient.

[Date]
[Payer Name]
[Payer Street Address]
[Payer City, State, and Zip Code]
Patient Name: [Patient Full Name]
Date of Birth: [Patient Birth Date]
Member ID: [Patient Member ID Number]
Policy or Group Number: [Patient Policy or Group Number]
Case ID Number: [Case ID Number (if available)]

To Whom It May Concern,

I am writing on behalf of my patient, [patient name], to request reconsideration for the coverage of FOTIVDA® (tivozanib) treatment which was denied on [date] for the following reason: [describe reason given in denial letter]. For your convenience, I have attached documentation supporting my request for reversal of coverage denial:

- ◅ The prior authorization request for [patient name] which was denied on [date]
- ◅ The patient's relevant medical history, diagnosis, and treatment plan
- ◅ Clinical rationale supporting FOTIVDA treatment for [patient name]

Patient's Clinical/Medical History

- ◅ [Patient's ICD-10-CM diagnosis code and date of diagnosis]
- ◅ [Patient's first visit date and date of referral]
- ◅ [Severity of patient's condition]
- ◅ [Previous treatments including drug names and duration, responses to those treatments, and reason for discontinuation]
- ◅ [Patient's disease progression]
- ◅ [Any additional factors impacting FOTIVDA treatment selection]

Treatment Plan

- ◅ [Include plan of treatment: dosage, frequency, and length of treatment]
- ◅ [Clinical rationale for the use of FOTIVDA]

Summary

Given the provided evidence, I am confident you will agree treatment with FOTIVDA is medically necessary. It is crucial that [plan name] allow the use of FOTIVDA and provide coverage so [patient name] receives the care they need. We appreciate your prompt review and reconsideration of this case. If you need additional information, please contact my office at [insert office phone number].

Sincerely,

_____

[Physician Name]
[Physician Address]
[Physician Phone]

Enclosures: [Full prescribing information, patient medical history, clinical notes, relevant peer-reviewed articles, clinical practice guidelines, FDA approval letter, etc.]

CLICK HERE TO ACCESS THE SAMPLE LETTER OF APPEAL

BEST PRACTICES TO SUBMIT MEDICAL EXCEPTIONS REQUEST:

A formulary Exception Request is typically used when the drug that is being prescribed is not covered or is restricted under the plan's formulary. To initiate the process of submitting an Exceptions Request, complete the following steps:

STEP 1: ASSESSMENT OF EXCEPTION REQUEST

An Exception Request may be submitted if:

- ☐ The drug is not on the plan's formulary but is necessary for the patients treatment.
- ☐ The drug is on the formulary but has specific restrictions, such as step therapy or quantity limits, however these restrictions are not appropriate for the patient's condition.
- ☐ Alternatives on the formulary are not effective or may cause adverse side effects which are not expected with the prescribed non-formulary drug.

STEP 2: BENEFITS INVESTIGATION

- ☐ Conduct a benefits investigation to determine the health plan's specific coverage criteria for FOTIVDA® (tivozanib)
- ☐ Check the plan's website or contact them by phone to determine if they have a Formulary or Tier Exception form.
  - *You may submit an Exceptions Request if your patient was previously on FOTIVDA, and the plan changed the formulary to exclude the medication or moved it to a higher tier.*
- ☐ Consider writing a specific Letter of Medical Necessity that explains the patient's diagnosis and the reason for the Exceptions Request.
  - *Prior Authorization Checklist on page 4*

SAMPLE LETTER OF MEDICAL EXCEPTION

Below is a template for your reference when drafting a Letter of Medical Exception. The information contained in this sample letter is provided for informational purposes only.

If this Exception Request has been previously been denied, consider including:

This is a letter of medical exception. I have included a copy of the original denial letter and medical notes in response to the denial.

For previously denied appeals, include the following:

- A copy of the denial letter
- Medical notes, written by the prescribing physician, in response to the denial letter

Sample Letter of Medical Exception

Instructions for Use:

Below is a template for your reference when drafting a Letter of Medical Exception. Please submit your letter on your office letterhead and replace all bracketed information with the patient-specific information.

As a reminder, the information contained in this sample letter is provided for informational purposes only. Providers are responsible for identifying and including any payer-specific requirements to ensure the accuracy and completeness of all information and materials submitted when requesting coverage for an individual patient. Please refer to the full Prescribing Information for FOTIVDA® (tivozanib) when determining whether the therapy is clinically appropriate for your patient.

[Date]
[Payer Name]
[Payer Street Address]
[Payer City, State, and Zip Code]
Patient Name: [Patient Full Name]
Date of Birth: [Patient Birth Date]
Member ID: [Patient Member ID Number]
Policy or Group Number: [Patient Policy or Group Number]
Case ID Number: [Case ID Number (if available)]

To Whom It May Concern,

I understand that the [plan name] policy for [patient name] requires [restriction description] prior to the approval of FOTIVDA® (tivozanib) treatment. However, I believe that [patient name] requires FOTIVDA without [restriction description] due to clinical and medical circumstances. Please see below for details about symptoms, previous treatments, medical history, and treatment rationale that supports the claim for medical exception for [patient name].

Patient's Clinical/Medical History

- [Patient's ICD-10-CM diagnosis code and date of diagnosis]
- [Patient's first visit date and date of referral]
- [Severity of patient's condition]
- [Previous treatments including drug names and duration, responses to those treatments, and reason for discontinuation]
- [Patient's disease progression]
- [Any additional factors impacting FOTIVDA treatment selection]

Justification for Medical Exception

- [State the clinical rationale for treatment with FOTIVDA]
- [Describe why the plan requirement is not appropriate for your patient]
- [List concerns that may include experience on similar therapies, drug side effects, and any other patient-specific considerations]

Treatment Plan

- [Include plan of treatment: dosage, frequency, and length of treatment]
- [Clinical rationale for the use of FOTIVDA]

Summary

Based on the above, I am certain that you will agree FOTIVDA is an appropriate treatment for [patient name]. A timely approval of FOTIVDA by [plan name] without [restriction description] would be greatly appreciated by both myself and my patient. Please contact me at [phone number] if you need more information to approve a medical exception for [patient name].

Sincerely,

_____

[Physician Name]
[Physician Address]
[Physician Phone]

Enclosures: [Full prescribing information, patient medical history, clinical notes, relevant peer-reviewed articles, clinical practice guidelines, FDA approval letter, etc.]

CLICK HERE TO ACCESS THE SAMPLE LETTER OF MEDICAL EXCEPTION

AVEO ACE
Access Center of Excellence

AVEO ACE CAN HELP

AVEO ACE is a comprehensive program dedicated to providing personalized support throughout the FOTIVDA journey.

Appeals Support

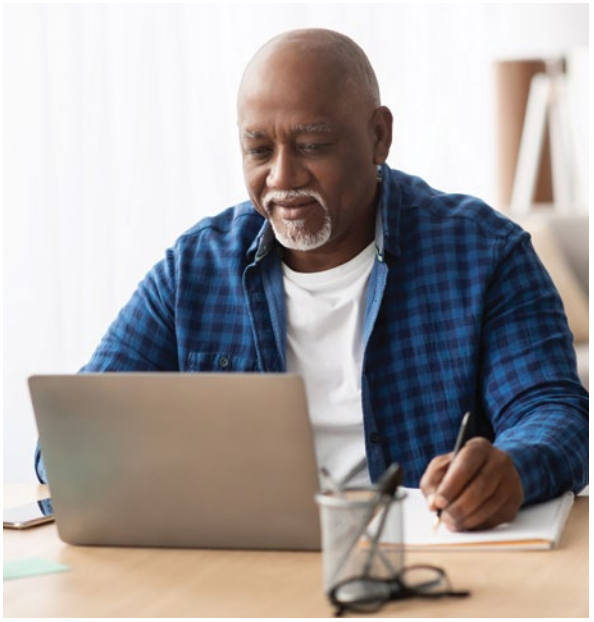
Reach out to AVEO ACE if you need assistance or have questions regarding a prior authorization or appeal.

Quick Start

Ask an AVEO ACE Specialist about the Quick Start program which provides medication to the patient at no cost if there are delays in obtaining coverage.

Financial Assistance

An AVEO ACE Specialist can help explore financial support options that many be able to help lower the cost for FOTIVDA.



GETTING STARTED WITH THE AVEO ACE PROGRAM:

CLICK HERE

To enroll online or **to download the form** and **fax to 1-888-920-2830**. Once the Enrollment Form is received, an AVEO ACE Program Specialist will follow up with you and your patient regarding next steps.

IF YOU HAVE ADDITIONAL QUESTIONS, CONTACT US AT:

CALL US AT:
1-833-FOTIVDA
(1-833-368-4832) M-F 8 AM to 8 PM ET

VISIT US AT:
WWW.FOTIVDA.COM

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