APPEALS PROCESS

Your plan offers you an appeals process if you have been denied care. You may call VIVIO Health for details at 1-800-470-4034 or find the details at MyVIVIO.com/appeals.

Appeals administration

If a member or physician requests an appeal and additional information is provided, it is reviewed and evaluated by the VIVIO Health appeals unit to determine if the drug use meets coverage conditions specified or intended by your employer according to the procedures set forth below:

Level 1: The VIVIO Health Appeals Unit
Level 2: The VIVIO Health Appeals Unit or external third party review organization
Level 3: Review by Independent Review Organization (IRO)

Appeal procedures apply to appeals of adverse benefit determinations of appropriateness, effectiveness and experimental classification of a specialty drug therapy. Appeals related to eligibility to participate in the plan are coordinated by your employer.

Appeals process

Level 1 Appeal: The VIVIO Health Appeals Unit	Timeframe
Written request to VIVIO Health	180 days from denial
Notification acknowledgement to claimant	2 days
Time allowance for participant to submit additional information	5 days (non-expedited)
Notification of benefit determination to claimant	15 days (pre-service) 30 days (post-service)

To initiate a level 1 appeal, a Plan Participant or Provider must submit a written request for an appeal to VIVIO Health within one hundred eighty (180) days of receipt of a notice of denial of medicine(s) under the Plan. VIVIO Health will evaluate and make a determination. For standard cases, the Participant will receive in writing within two (2) working days an acknowledgement of receipt of the appeal request, which includes allowance of five (5) business days for the Participant to submit any additional information.

Level 2 Appeal: The VIVIO Health Appeals Unit	Timeframe

or external third-party review organization	
Written request to VIVIO Health	90 days from Level 1 adverse determination
Notification acknowledgement to claimant	2 days
Time allowance for participant to submit additional information	5 days (non-expedited)
Notification of benefit determination to claimant	15 days (pre-service) 30 days (post-service)

To initiate a level 2 appeal, a Plan Participant or Provider must submit a written request for an appeal to VIVIO Health within ninety (90) days of receipt of an adverse determination of a Level One appeal under the Plan. VIVIO Health will evaluate internally or use an external organization to make a determination. For standard cases, the Participant will receive in writing within two (2) working days an acknowledgement of receipt of the appeal request, which includes allowance of five (5) business days for the Participant to submit any additional information.

Level 3 Appeal: Independent Review Organization (IRO)	Timeframe
Written request to VIVIO Health	120 days from Level 2 adverse determination
Notification acknowledgement to claimant	2 days
Time allowance for participant to submit additional information	10 days (non-expedited)
Notification of benefit determination to claimant	45 days

To initiate a level 3 appeal, a Plan Participant or Provider must submit a written request for an appeal to VIVIO Health within ninety (120) days of receipt of an adverse determination of a Level Two appeal under the Plan.

An IRO is external to both VIVIO Health and your employer, and utilizes independent medical professionals with appropriate expertise to perform external reviews of appeals. In rendering a decision, the IRO will consider any appropriate additional information submitted by the Participant and will follow the plan documents governing the Participant's benefits.

For claims involving urgent care, a Participant may request an expedited external review if the adverse benefit determination involves a medical condition of the Participant for which the regular time frame would seriously jeopardize the life or health of the Participant or

would jeopardize the Participant's ability to regain maximum function, and the Participant filed a request for an expedited internal appeal; or, if the final internal adverse benefit determination involved a situation where the Participant had a medical condition where that time frame would pose such jeopardy, and if the final internal adverse benefit determination concerned an admission, availability of care, continued stay or health care service for which the Participant received emergency services and was not discharged from a facility.

Individuals in urgent care situations and individuals receiving an ongoing course of treatment may proceed with an expedited external review by an IRO at the same time as the internal review process occurs.

There are no fees or costs imposed on a Participant for the external review of an appeal. The Participant's decision as to whether or not to submit a denied appeal for external review will have no effect on the Participant's rights to any other benefits under the Plan.

If a Participant files a request for an external review of an appeal with an IRO:

- The external review may only be requested after exhaustion of the required Internal Appeal procedures under the Plan, unless an expedited external review of a claim involving urgent care or an ongoing course of treatment is requested. Accordingly, the Participant must first submit an appeal with VIVIO Health and receive a denial of appeal before requesting an external review of an appeal with an IRO.
- After a Participant receives a denial of an appeal, the Participant must submit the request for external review of appeal with IRO in writing within 120 days from the date of receipt of the adverse benefit determination, extended to the next working day if the date falls on a weekend or federal holiday.
- IRO will forward a copy of the final appeal denial letter and all other pertinent information that was reviewed in the appeal to the IRO. The Participant may also submit additional information to be considered. For standard non-expedited appeals, the Participant will have ten (10) business days to submit additional information to the IRO.
- Within five days after receipt of the request for external review, the Plan will complete a preliminary review to determine if the Participant was covered under the Plan at the time the service was requested or provided; whether the adverse benefit determination relates to the Participant's failure to meet the eligibility requirements of the Plan; whether the Participant has exhausted the Plan's internal appeal process; and whether the Participant has provided all of the information and forms required to process an external review. Within one business day after completion of this preliminary review, the Plan will provide the Participant written notification giving any reasons for the ineligibility of the request for external review and describing the information or materials required, and the Plan will allow the Participant to perfect a

request for external review within the four month filing period or within the 48 hour period following receipt of the notification, whichever is later.

- The Participant will be notified of the decision of the IRO within 45 days of the receipt of the request for the external review of an appeal for standard, non urgent claims. The IRO's decision will include:
    a) A general description of the reason for the request for external review;
    b) The dates the IRO received the assignment to conduct the external review and the date of their decision;
    c) Reference to the evidence or documentation, including specific coverage provisions and evidence-based standards, considered in reaching their decision, taking into account adequate clinical and scientific experience and protocols with respect to claims involving experimental of investigative treatments;
    d) A discussion of the principal reason or reasons for its decision, including the rationale for its decision;
    e) A statement that judicial review may be available; and
    f) Current contact information, including the phone number for any ombudsman established under the PHS Act.
    g) In the event of an expedited external appeal for claims involving urgent care, the IRO will make the decision as expeditiously as the Participant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review and, if the notice is not in writing, within 48 hours after the date of providing the verbal notice, the IRO will provide written confirmation of the decision to the Participant and the Plan. Written notice must be provided in a linguistically appropriate manner. The notice will provide the opportunity to request diagnosis and treatment codes and their meanings.
    h) The decision of the IRO will be binding on the Participant as well as the Plan, except to the extent there may be other remedies available under state law.
- The statute of limitations or other defense based on timeliness is suspended during the time that an external review of your appeal is pending.

Experimental or investigational drug exclusions

Experimental or Investigational drug therapies may not be a covered benefit for your plan. A drug therapy is considered Experimental or Investigational unless it meets all seven of the following criteria:

- The drug must have a standard approval from the FDA including phase III trials
- The scientific evidence as published in peer-reviewed literature must permit conclusions concerning the effect of the drug on health outcomes;

- The drug must improve the net health outcome;
- The drug must be as beneficial as any established alternatives
- The improvement must be attainable outside the Investigational settings
- The drug must have clearly defined and accepted outcomes that have a direct correlation to improved quality of life or increase life expectancy
- The drug must have a significant likelihood of meeting the defined endpoint (efficacy) in the identified patient population

Timeframes for processing standard appeals

Standard, non-expedited Level 1 and 2 appeals involving the review of a denial of coverage for medicines requests will be completed within 15 calendar days for pre-service appeals and 30 calendar days for post-service appeals. The appeal review period may be extended for a maximum of ten (10) calendar days if: 1) there is reasonable cause beyond the reviewer's control for the delay; 2) can show that the delay will not result in increased medical risk to the Participant; and 3) provide a written progress report to the Participant and the related provider within the forty (40) day review period. Participants must agree, in writing, to a request to extend a deadline. Some appeals of denials relating to claims involving urgent pharmaceutical care are processed on an expedited basis. Expedited decisions are made when a Participant's life or health or ability to regain maximum function would be jeopardized by following the standard appeal process and time frames; or, in the opinion of an attending provider with knowledge of the Participant's medical condition, would subject the Participant to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim. In cases that require an expedited decision of a Medicine request, based at the request of an attending provider or Participant, a decision will be made within seventy-two (72) hours of the receipt of the request or more rapidly depending on medical exigencies. If a Participant requests an expedited decision, the request will be reviewed. If it is determined that the request for an expedited appeal is medically necessary, a decision will be made within seventy-two (72) hours of the request or more rapidly depending on medical exigencies. All required information will be transmitted between the reviewer, the applicable provider, and the Participant by the quickest means possible. If it is determined that a request for an expedited appeal is not medically necessary, the Participant will be notified and the appeal processed within fifteen (15) calendar days.