

Coverage Determinations & Appeals

Coverage Determinations (Exceptions) Can be Sought From PDPs for the Following Issues:

- Cost-sharing or tier status of a drug
- UM requirement for a drug
- Drug not included on PDP formulary

Who Can File for a Coverage Determination?

- The Enrollee
- An Appointed representative of the enrollee
(varies by state)
- The Physician who prescribed the medication

Determine Specific Requirements For Filing for a PDP Coverage Determination

(Each PDP will establish its own contact
and documentation requirements)

At Least 3 Things Must Be Established

1. The medical necessity of the prescribed drug; and
2. The other drugs on the formulary will not be as effective or
3. Will have an adverse effect, or
4. Both 2 & 3

Appeals Process

There are 6 levels of appeal under Part D:

- 1. Coverage Determination** (or exception) from the PDP
- 2. Redetermination** by the PDP
- 3. Reconsideration** by an Independent Review Entity (IRE)
- 4. Hearing** by an Administrative Law Judge (ALJ)
- 5. Review** by a Medicare Appeals Council (MAC)
- 6. Judicial Review** in a District Court

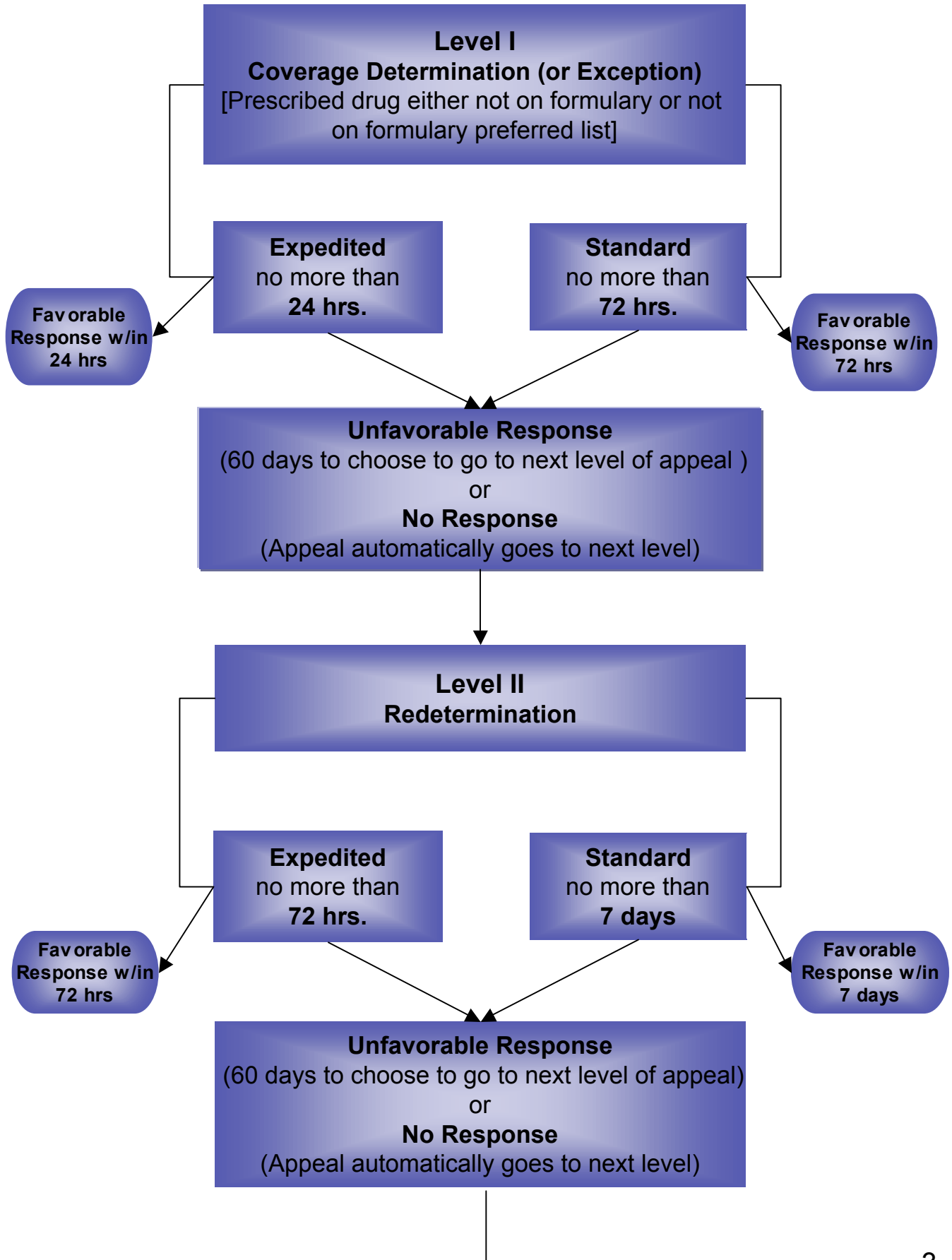
**An appeal may be either
*standard or expedited.***

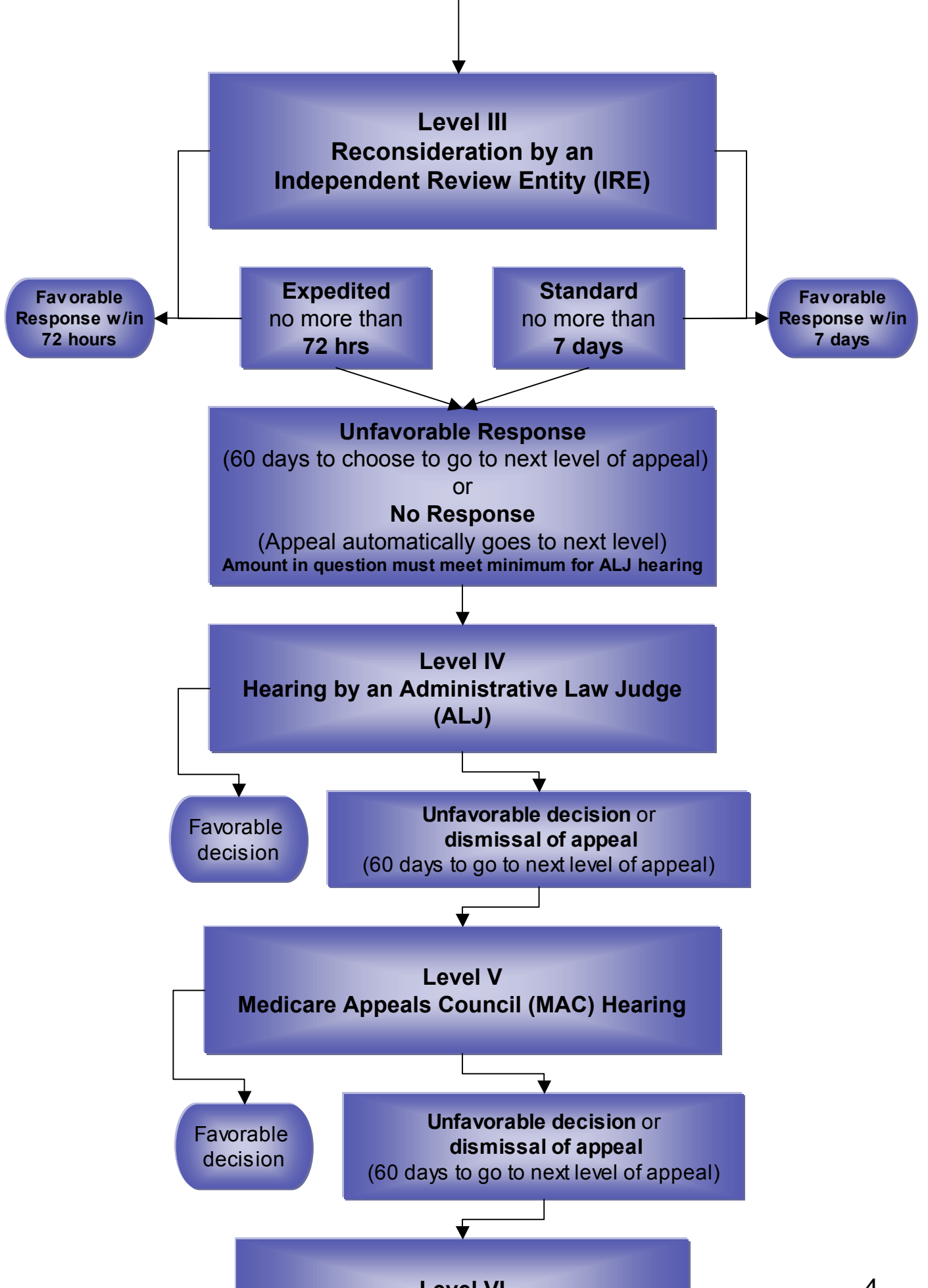
Although the enrollee or the enrollee's representative may request an expedited appeal, the PDP may determine if a standard appeal is adequate. If a physician requests an expedited appeal, the PDP is required to honor that request.

A PDP may take no more than 72 hours to issue a standard coverage determination (the first level of appeal), or no more than 24 hours to issue an expedited determination. At each of the next two levels of appeal, a standard appeal may take up to 7 days, while a decision on an expedited appeal must be reached within 72 hours. The ALJ Hearing, MAC Review, and Judicial Review levels do not make a distinction between expedited and standard appeals.

The following pages provide details on each level of appeal.

How an Appeal Proceeds





Level I: Coverage Determination

A coverage determination, or exception, may be requested from a PDP if the PDP deems that a drug is not medically necessary, if a medically necessary drug is not on the PDP formulary, if the drug is on the formulary as other than a preferred drug (i.e., it requires a higher co-pay), or if a utilization management tool such as step therapy is required before the enrollee can obtain the necessary drug. The request may be made by the enrollee, by the enrollee's appointed representative, or by the prescribing physician.

Although each PDP is required to have coverage determination procedures that it disseminates to its enrollees at the time of their enrollment, at this time there is no clear, standardized definition of what these procedures should be. Issues such as what method the individual requesting the determination must use to communicate the request to the PDP and what form the PDP's response should take have yet to be codified. While the regulations say a physician may request a coverage determination orally, a written statement may also be required.

The information provided below is everything that we currently know about how a coverage determination will work.

Standard Coverage Determination

If a standard coverage determination is requested, the PDP must respond to the request within 72 hours after receipt of the request. If there is an unfavorable response, the enrollee, the enrollee's representative, or the prescribing physician may request a redetermination, or Level II of the appeals process. If the PDP fails to respond to the request within 72 hours, the appeal automatically moves on to the next level of appeal.

Expedited Coverage Determination

If an expedited coverage determination is requested and granted, the PDP must respond "as expeditiously as the enrollee's health condition requires," but no later than 24 hours after the request is received. If the prescribing physician requests an expedited coverage determination, stipulating that the standard timeframe "may seriously jeopardize the life of health of the enrollee or the enrollee's ability to regain maximum function" the PDP must grant it, whereas if an expedited coverage determination is requested by the enrollee or enrollee's representative, the PDP has the option of deciding a standard coverage determination will suffice. If there is an unfavorable response, the enrollee, the enrollee's representative, or the prescribing physician may request a redetermination, or Level II of the appeals process. If the PDP fails to respond to the request within 24 hours, the appeal automatically moves on to the next level of appeal.

Level II: Coverage Redetermination

A coverage redetermination may be requested from a PDP within 60 days after a PDP gives an unfavorable response to a request for a coverage determination. According to the regulations, a redetermination must be requested in writing, although a PDP may elect to accept oral requests. The 60-day timeframe may be extended if the enrollee submits a written request stating why the deadline was not met. If the PDP failed to respond to the request for a coverage determination within the required timeframe (72 hours for a standard; 24 hours for expedited) the appeal automatically moves on to the next level of appeal, or the coverage redetermination.

The PDP remains the reviewing entity for the redetermination. However, if the issue disputed is the denial of coverage based on medical necessity, the redetermination must be made by a physician “with expertise in the field of medicine that is appropriate for the services at issue, although the reviewing physician need not be of the same specialty as the prescribing physician.” The redetermination is a review of an adverse coverage determination, “the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor [PDP] obtains.” The PDP must provide the enrollee or prescribing physician with a “reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing.”

As with the coverage determination, an enrollee, an enrollee’s representative, or the prescribing physician may request and expedited coverage redetermination, or the physician can provide oral or written support for the enrollee’s request. If the request comes from the physician, indicating that the standard timeframe “may seriously jeopardize the life or health of the enrollee or the enrollee’s ability to regain maximum function,” an expedited redetermination must be provided.

Standard Coverage Redetermination

If a standard coverage redetermination is requested, the PDP must respond in writing with its decision within 7 days after the receipt of the request. (It is unclear whether the 7 days begins 24 hours after the deadline was missed, or exactly when.) If the PDP fails to provide a decision within that timeframe, the appeal automatically moves to the next level of appeal, or the review by an independent review entity (IRE).

Expedited Coverage Redetermination

If an expedited coverage redetermination is requested (or, presumably, if the PDP failed to meet the timeline for the expedited coverage determination—but it is unclear whether they’re allowed to do that), the PDP must return a decision in writing within 72 hours after the request was received. The PDP is required to request, within 24 hours after the request for an expedited redetermination is received, any necessary medical information needed for making its redetermination. If a decision is not provided within this timeframe, the appeal automatically moves on to the next appeal level, the IRE review.

Level III: Reconsideration by Independent Review Entity

A reconsideration by an Independent Review Entity (IRE) may be requested if the enrollee is not satisfied with the redetermination decision made by the PDP. The enrollee must file a written request for the reconsideration within 60 days of the redetermination decision. If the PDP failed to respond with a redetermination decision within the appropriate timeframe, the appeal automatically moves on to the IRE reconsideration.

The IRE is “required to solicit the views of the prescribing physician.” If the redetermination decision was not to provide a drug that is not on the PDP’s formulary, the prescribing physician “must determine that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both.” The IRE is required to conduct the reconsideration as “expeditiously as the enrollee’s health condition requires,” but may not exceed 72 hours for an expedited request or 7 days for a standard request.

When the IRE makes its determination, it is responsible for sending notice of its decision in writing to the enrollee, the PDP, and to the Centers for Medicare and Medicaid Services (CMS). The notice must be written in understandable language and must state the specific reasons for the decision reached.

If the decision reached fails to reverse the PDP’s coverage redetermination, the IRE notice must inform the enrollee of the right to an administrative law judge (ALJ) hearing if the amount of money in question meets the “threshold requirement” that is established annually by the secretary of HHS and describe the procedures that need to be followed to obtain an ALJ hearing; as well as “any other requirements specified by CMS,” also undefined.

The IRE decision is considered final unless the enrollee files a request for an ALJ hearing.

Level IV: The Administrative Law Judge (ALJ) Hearing

To determine whether the threshold amount that is required for an enrollee to be granted an ALJ hearing has been met, CMS uses the projected value of the drug benefits that are being denied over one year. Appeals for two or more drugs can be aggregated to reach this amount, or two or more enrollees facing the same issue can aggregate their appeals to meet the threshold. (Because of confidentiality issues relating to medical care, it is unclear how enrollees would be able to connect to do such an aggregate appeal.)

An enrollee who is entitled to an ALJ hearing, must file a written request for such a hearing “with the entity specified in the IRE’s reconsideration notice.” Unless a request for an extension has been granted by the ALJ, the request must be filed within 60 days of the date of the notice of the IRE reconsideration determination.

Level V: The Medicare Appeals Council (MAC) Hearing

An enrollee who is dissatisfied with the decision of the ALJ may request a MAC hearing to review the ALJ’s decision or dismissal of the appeal. The MAC review is the final decision from CMS on the enrollee’s appeal. If the MAC denies the request for the review or decides against the enrollee, the enrollee can move on to the next level of appeal, the judicial review.

Level VI: The Judicial Review

To obtain a judicial review, the enrollee must file a civil action in a U.S. district court. This action must be filed within 60 days after the decision of the MAC has been handed down.