

NENC Medicines Subcommittee Appeals Policy

An appeal may be made on two grounds: processes or against a recommendation made by the NENC Medicines Subcommittee or its Subgroups.

Appeals against process used for decision making:

Appeals against NENC medicines governance processes will be considered by the NENC Medicines Subcommittee however all appeals should be made to the officers of the NENC Medicines Subcommittee in the first instance. Process appeals will be escalated by the NENC Medicines Committee to the NENC ICB Executive Committee as necessary. Please note that all process appeals must be made within three months of the meeting taking place.

Appeals against decisions or recommendations:

Notice of an appeal against decisions or recommendations made by the NENC Medicines Subcommittee and/or its Subgroups must adhere to the following process:

1. The appeal is made by NHS employees within the region covered by the NENC ICB or by a clinician outside of the region who has responsibility for a patient residing within the above ICB and for the indication or use for which the NENC Medicines Subcommittee considered the treatment.

Please note appeals from pharmaceutical companies will not be accepted.

2. There are sufficient grounds for an appeal i.e.
 - a. Significant new published peer reviewed evidence has become available, and this evidence could affect the original decision by altering the balance of risks and benefits of the proposed treatment and/or the cost-effectiveness of the treatment.
 - b. The applicant can demonstrate that not all relevant evidence was taken into consideration at the time of the decision for whatever reason.

Anyone who wishes to appeal against the decision-making process of the group with regard to the decision in question will be required to present substantial evidence as to the reasons behind their appeal.

Applications for a medicine on which a decision has already been made can only be resubmitted to the group if substantial and significant new evidence becomes available, or one of the grounds for appeal is met.

1. Application to appeal

An appeal can be made of the decision making process or of the actual decision.

Appeals against **NENC Medicines Subcommittee processes** will be considered by the NENC Medicines Subcommittee however all appeals should be made to the officers of the NENC Medicines Subcommittee in the first instance. Please note that all process appeals must be made within three months month of the meeting taking place.

Notice of an appeal against a decision must adhere to the following process:

- 1.1. An application to appeal must be made to the group secretary in writing, including via e-mail if preferred. Notice of intent to appeal can be made verbally although this must be followed with an application in writing. The appellant should indicate the basis or grounds of the appeal (see section 2). The professional secretary will ensure that the appeal is passed onto the group/subgroup that initially made the decision or recommendation.
- 1.2. There is a six month time limit on making an appeal of a NENC Medicines Subcommittee decision except that all process appeals must be made within three months of the meeting taking place. After six months a resubmission with a new application is required.
- 1.3. There are no limits on the number of appeals that can be made of a NENC Medicines Subcommittee decision. In considering an appeal each application will be judged on its own merits and in isolation of all previous applications to appeal the same decision. Appellants should submit one co-ordinated appeal rather than several relating to one decision.
- 1.4. If so requested, the professional secretary will act as an impartial adviser to prospective appellants regarding the process and other aspects.
- 1.5. An application to appeal a decision will be considered by the officers of NENC Medicines Subcommittee (chair, deputy-chair, and secretary) and the appellant will be notified if the request to appeal is granted at the earliest opportunity. Clinical/specialist advice will be sought if necessary.
- 1.6. All confirmed applications to appeal a decision will be relayed to group members at the next meeting. If there is a case for appeal, then it will be added to the agenda of the next available meeting.
- 1.7. If an application to appeal is rejected and the applicant is not satisfied with this decision the application for appeal will be considered by NENC Medicines Subcommittee at their next available meeting and the appellant will be informed of the

decision following that meeting.

2. Appeal hearing process

2.1. If an application to appeal a decision is granted the secretary will arrange for the appeal to be considered at the next mutually convenient meeting of the NENC Medicines Subcommittee or the appropriate subgroup.

2.2. Where necessary the original formulary application should be amended to include the new evidence and any new references should be supplied by the appellant.

2.3. An appellant, or their named deputy, will be invited to:

- Submit any supporting evidence or documentation to the secretary for circulation to group members prior to the meeting at which the appeal is scheduled. Declarations of interest must also be submitted at this stage.
- Attend the meeting at which the appeal is scheduled only for that part of the meeting pertaining to the appeal.
- The appellant will have the opportunity to present any data or points of argument that they wish during the meeting. Such a presentation can take any form, for example a visual presentation using digital projection, or a verbal presentation, or a less formal open discussion with group members.
- Stay in attendance at the meeting immediately following their presentation and inform further discussion and answer any questions.
- Appellants will then be requested to depart the meeting to permit the group to continue discussion and deliberation in camera.

2.4. As a guide, it is envisaged that a maximum of 30 minutes will be scheduled for an entire appeal hearing, approximately broken down into 10 minutes for each of presentation, discussion and deliberation as described previously.

2.5. Appellants and their deputies must:

- Inform the secretary as to who will be attending the NTAG meeting to present the appeal, if indeed anyone is to attend. A mutually convenient time slot will then be set so that the appellant need only attend for that part of the meeting pertaining to their appeal.
- Provide an electronic copy of any presentation that they wish to make during the meeting, at least seven days prior to the meeting for circulation to NTAG members. Any confidential data should be clearly indicated.

- Complete a declaration of interest form, or otherwise declare any potential competing interests.

2.6. Once an appeal has been heard the group may opt to:

- Reject the appeal and leave their decision unchanged.
- Accept the appeal or any part of it and amend their decision accordingly.
- Defer their decision, leaving the current recommendation unchanged and valid, pending further information.

2.7. If the appeal is made on a subgroup decision, then the subgroup will need to get approval on the outcome of the appeal by the NENC Medicines Subcommittee. The standard front sheet should be filled in with details of the appeal, the recommendation being contested, and the appeal decision made by the subgroup. This must be submitted to the NENC Medicines Subcommittee for approval at the next available meeting.

2.8. The outcome of the appeal will be communicated to the appellant and published as a decision summary on the NTAG website within seven days of the appeal hearing.

2.9. No further appeals can be made based on the same points.

2.10.

In the event that the appeal held by a subgroup is unsuccessful (i.e. the original decision of the subgroup/group is upheld) the applicant may request that the appeal is considered again and separately by the NENC Medicines Subcommittee. Any members who were involved in the original subgroup decision and/or appeal cannot be involved in considering this appeal again at NENC Medicines Subcommittee; it is therefore best if voting membership between the main group and subgroups does not overlap. Where the decision relates to the NENC Medicines Subcommittee then the applicant can request a review of the decision by NENC ICB Executive Committee.

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Based on previous NTAG appeals process