



Clinician and Patient Involvement Group (CAPIG)

Terms of Reference

1. Purpose and remit:

The Clinician and Patient Involvement Group (CAPIG) meeting is an additional stage in the AWMSG appraisal process which is held if a medicine for a **very** rare disease is not recommended for routine use within NHS Wales by the appraisal committee. The aim of CAPIG is to identify and discuss in more detail any additional benefits of the medicine from a clinician and patient perspective. The additional information gathered from the CAPIG meeting will be presented to AWMSG as a report giving further information from a patient's and clinician's perspective to help AWMSG when making a decision.

CAPIG will consider:

- Aspects of additional value to the patient, for example, ability to work or continue in education, convenience of treatment, ability to maintain independence and dignity.
- The degree of severity of the disease in terms of survival and quality of life impact on patients and their families or carers.
- Whether the medicine addresses an unmet need, for example, there are no other licensed medicines.
- Whether the medicine can reverse or cure, rather than stabilise, the condition.
- Whether the medicine may bridge a gap to a 'definitive' therapy (such as a gene therapy) and that this 'definitive' therapy is currently in development.
- Whether there are any specific patient groups for whom the medicine is particularly beneficial.
- A supplementary cost-consequence analysis (optional).

2. Membership:

Chair

Meetings will be chaired by an individual with extensive experience of health technology appraisal and patient involvement.

PAPIG representative

One representative from AWMSG's Patient and Public Interest Group (PAPIG).

Patient organisation representatives

Representatives from appropriate patient organisations or nominated individual patient experts; up to 3 organisations may be represented.

Clinical experts

Clinical experts are normally nominated by a specialist advisory group (up to 3 clinical experts). Clinical experts are likely to be consultant level doctors; however, when appropriate, they may be clinical nurse specialists or clinical pharmacists.

Public representative,

One public representative usually nominated by Community Health Councils.

AWMSG Lay member

One member or deputy from AWMSG

The applicant company

The applicant company will be invited to attend and present a short statement at the meeting (maximum of two representatives). They may input into discussions but will leave the meeting before completion of the CAPIG report template or agreement of the final statement.

AWTTC will provide the following secretariat support:

- Appraisal Lead
- Administrator or medical writer
- Liaison Manager

3. Reporting responsibilities:

The output of a CAPIG meeting will be a report highlighting the added value of a medicine from a patient and clinician perspective. This information will be presented to AWMSG.

4. Meetings:

CAPIG meetings will be scheduled as needed.

Attendance in person is preferable; however, where necessary, members may join the meeting by teleconference or video conference.

The following papers will be forwarded to CAPIG members at least one week before the meeting:

- The submitted views of clinical experts
- The submitted views of patients, carers and patient organisations and
- Cost consequence analyses (if submitted by the company).

CAPIG members will be required to declare any conflicts of interest and sign a confidentiality agreement

5. Quorum:

The meeting quorum will be one clinician and one patient organisation representative in attendance in addition to the Chair.

6. Record of business:

A report will be prepared by the AWMSG Secretariat (AWTTC) and the content will be agreed by CAPIG members. This document will be included in the AWMSG meeting papers.

7. Review:

The Terms of Reference will be reviewed annually.