Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Clinician and Patient Involvement Group (CAPIG) Information

This document provides information on the Clinician and Patient Involvement Group (CAPIG), which is part of the All Wales Medicines Strategy Group (AWMSG) health technology appraisal process for medicines used to treat a very rare disease.

About the All Wales Medicines Strategy Group (AWMSG)

AWMSG has the remit to appraise newly licensed medicines, including licence extensions and/or new formulations of medicines. AWMSG's advice is based on clinical effectiveness and cost-effectiveness, as well as the anticipated budgetary impact and broader societal and equity issues. AWMSG's recommendations are provided to Welsh Government, who will take account of AWMSG's advice when making a final decision about whether a medicine should be routinely available in NHS Wales.

AWMSG considers:

- How well the medicine works;
- Which patients would benefit from receiving the medicine;
- How does it compare to currently used treatments;
- How the medicine affects the quality of a patient's life; and
- How much the medicine costs compared with the other treatment options.

An assessment of the evidence provided by the medicine's marketing authorisation holder, as well as any other available information, is carried out by the All Wales Toxicology & Therapeutics Centre (AWTTC). The assessment report (ASAR) is first considered by the New Medicines Group (NMG), a sub-committee of AWMSG, which meets in private and considers only the scientific evidence. NMG's preliminary recommendation (PAR), and the manufacturer's response, are subsequently considered and discussed at the AWMSG public meeting. AWMSG take into account the budget impact and wider societal issues. AWTTC also gathers information from patients, patient organisations and support groups about how people are affected by the condition and the potential impact of the new medicine on patients and their families or carers. The evidence submitted by the manufacturer to support the use of the medicine within NHS Wales is presented and discussed at the NMG and AWMSG meetings. For more detailed information regarding the assessment process please see the website at: www.awmsg.com

What is CAPIG and when is it used?

The 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.

How will the new process work?

In making a submission for appraisal by AWMSG, the applicant company will be asked to state whether the medicine should be considered as a medicine for a very rare disease, and to provide evidence to support this.

The medicine will be appraised by NMG, who will make a preliminary appraisal recommendation (PAR) to AWMSG. If NMG's recommendation is negative, that is, NMG does not support use of the medicine within NHS Wales, a CAPIG to be convened.

Who will take part in a CAPIG meeting?

Chairman
AWMSG Patient and Public Interest Group (PAPIG) representative
Patient organisation / patient support group representatives
Clinical experts (maximum 3 - usually nominated by the specialist advisory group)*
Public/lay representative (usually nominated by Community Health Councils)
AWMSG lay member and/or deputy
Applicant company representative in non-voting capacity**
AWTTC appraisal lead (non-voting capacity)
AWTTC administrator/medical writer (non-voting capacity)
AWTTC Liaison Manager (non-voting capacity)

*Clinical experts are likely to be consultant level doctors. However, when appropriate, they may be clinical nurse specialists or clinical pharmacists.

**The applicant company may attend and present a short statement at the meeting. They may take part in discussions but will leave the meeting before any voting, completion of the CAPIG report or agreement of the final statement.

Declarations of Interest and Confidentiality

Everyone who takes part in the CAPIG meeting must declare any conflicts of interest and sign a confidentiality agreement because information provided for the CAPIG meeting must be kept confidential.

What preparation is needed before a CAPIG meeting?

CAPIG will discuss how the medicine may affect a patient's quality of life and how it may impact on a patient's family or carers. The group will also consider issues such as the severity of the condition, any unmet need, the added value of the medicine for the patient, the patient's family or carers, where in the patient pathway the medicine could most appropriately be used, specific patient groups that may benefit more from the use of the medicine, and any important considerations in relation to treatment delivery. It is important that evidence is gathered to support the above issues before the meeting takes place. In summary, discussion at the meeting will focus on patient and carer quality of life, such as:

- ability to continue work or education;
- management of symptoms such as pain and extreme tiredness;
- helping relieve psychological distress;
- convenience of how and where the treatment is received; and
- ability to self-care or maintain independence and dignity.

There may already be some evidence from patient organisations and clinicians' views. However, before the CAPIG meeting AWTTC will request a short statement highlighting any 'additional' key issues.

Companies can submit a supplementary cost-consequence analyses (CCA) at the CAPIG stage. A cost-consequence analysis template and supplementary cost-consequence analysis form are available. These analyses may be submitted by the applicant company in addition to the CAPIG statement and the primary cost-utility analysis submitted in the Form B. Providing the supplementary CCA analyses is optional.

How much time will I have to prepare for a CAPIG meeting?

AWTTC will confirm whether a CAPIG meeting will be held after negative advice from an appraisal committee. After the submitting company has confirmed that they wish AWTTC to convene a CAPIG meeting, you will have approximately one month to prepare for the meeting: written statements will be required two weeks before the CAPIG meeting.

What happens during a CAPIG meeting?

The Chairperson will guide everyone through the meeting and there will be opportunity to discuss and consider the views of all participants. A summary of the key points of discussion will be compiled in a report and the content will be agreed by the CAPIG members.

What happens after the CAPIG meeting?

The completed CAPIG report will be included in the AWMSG meeting papers along with the rest of the appraisal documentation and put on the AWMSG website. It will be a major factor in determining whether AWMSG will recommend the use of the medicine within NHS Wales.

Definitions

AWMSG considers medicines for very rare diseases as orphan, orphan-equivalent, ultra-orphan or ultra-orphan equivalent.

Orphan medicine (or orphan-equivalent)	A medicine with orphan status* (or a medicine without orphan status* with a prevalence** of ≤ 1 in 2,000 people in Wales [or the UK] for the full licensed population and meets the criteria for European Commission orphan status).
Ultra-orphan medicine (or ultra-orphan equivalent)	A subset of orphan medicines that have a prevalence of ≤ 1 in 50,000 people in Wales (or the UK) for the full licensed population (or a medicine without orphan status* and a prevalence** of ≤1 in 50,000 people in Wales (or the UK) for the full licensed population and meets the criteria for European Commission orphan status).

*Medicines granted orphan status by the European Commission meet these criteria[1]:

- A medicine intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating.
- The prevalence of the disease or condition in the EU must be ≤ 1 in 2,000 people, or it must be unlikely that marketing the medicine would generate sufficient returns to justify the investment needed for its development.
- No satisfactory method of diagnosis, prevention or treatment of the disease or condition can be authorised, or, if such a method exists, the medicine must be of significant benefit to those affected by the disease or condition.

** Prevalence figures apply to the full population of the licensed indication/s and should be based on national published figures or by consulting clinical experts and prescribing data if published figures are not available.

In applying these principles, AWMSG will use a degree of pragmatism to the appraisal of medicines used to treat very rare diseases when the patient population is small.