NICE consultation processes and where UKCPA can contribute

UKCPA
CLINICAL PHARMACY ASSOCIATION

Single Technology Appraisal (STA)

- Assesses a single drug or treatment
- Used for new technologies, usually new pharmaceutical products or license extensions for existing products
- Also used for reviews of some published appraisals

Week 0	Week 2	Week 9	Week 10	Week 12
NICE invite stakeholders to take part in the appraisal. Consultees have 8 weeks to submit a statement on the potential clinical and cost effectiveness of a treatment. UKCPA CLINICAL PHARMACY ASSOCIATION NICE ask the intervention technology company to produce a report of all relevant evidence - published and unpublished - for the appraisal. NICE add the remit, scope and a list of consultees and commentators to the NICE website. The remit is the brief for the appraisal. The scope sets out what the technology appraisal will cover and the questions that need to be addressed.	**Request for clinical, commissioning and patient experts** NICE ask the consultees to send in their clinical expert nominations. The NICE team and the chair of the Appraisal Committee selects experts from those nominated. Experts can submit statements and attend the appraisal committee meeting to present their views. UKCPA CLINICAL PHARMACY ASSOCIATION	An independent academic centre (called the Evidence Review Group) critiques the company's evidence submission and prepares a report on the clinical and cost effectiveness of the technology.	NICE invite the selected clinical, commissioning and patient experts to attend the appraisal committee. NICE ask them to submit a statement on the technology and how it should be used in the NHS in England. UKCPA CLINICAL PHARMACY ASSOCIATION	**Request for clarification sent to company** If the evidence submission is incomplete, NICE consult with the Evidence Review Group and send a letter of clarification to the company.

Week 17	Week 18	Week 19	Week 21	Week 24
Evidence report (ERG) received by NICE	ERG report sent to company for fact checking Deadline for receipt of the expert statements UKCPA CLINICAL PHARMACY ASSOCIATION	Key documents sent to the appraisal committee. The appraisal committee is an independent advisory committee that makes the recommendations.	NICE hold an appraisal committee meeting to consider the committee papers and hear from nominated clinical, patient and NHS commissioning experts. UKCPA CLINICAL PHARMACY ASSOCIATION The committee will decide to develop an appraisal consultation document (ACD) or final appraisal determination (FAD). The ACD contains the draft recommendations from the Appraisal Committee and is produced when the recommendations from the Appraisal Committee don't recommend use of the technology, or limit the use of the technology beyond the specifications in the marketing authorisation. The FAD is the final draft of the guidance and includes the committee's final recommendations. If an ACD isn't needed NICE move straight to developing the Final Appraisal Determination (FAD) (see week 29).	**Appraisal consultation document (ACD) and supporting documents sent out for comment** Consultee and commentators have 20 working days to submit comments on the draft recommendations. UKCPA CLINICAL PHARMACY ASSOCIATION

Week 25	Week 26	Week 27	Week 28	Week 29
Public consultation on the ACD The ACD and supporting documents are published on the website for comment. Anyone can submit comments during consultation.	**Final appraisal document (FAD) sent out to consultees and commentators (if no ACD produced)** Consultees have 15 days to appeal. UKCPA CLINICAL PHARMACY ASSOCIATION	Final appraisal document (FAD) published on NICE website (if no ACD produced)	Consultation on the ACD ends	**Appraisal committee meet to develop the FAD** The Appraisal Committee considers the comments received on the ACD, then makes its final recommendations on how the technology should be used in the NHS in England. This is the FAD.

Week 30	Week 34	Week 35	Week 37	Week 43
Guidance issued (if no ACD produced) If no ACD was produced, and no appeals have been received, the topic is published. This is the earliest possible point that final guidance can be issued.	**FAD and supporting documents sent to consultees and commentators** Consultees have 15 working days to appeal against the final recommendations in the FAD. UKCPA CLINICAL PHARMACY ASSOCIATION	**FAD published** NICE publish the FAD and supporting documents on the website for information.	**Close of appeal period** If no appeals have been received, the guidance is prepared for publication. If appeals have been received, the appeals process is followed.	**Technology appraisal published** If there are no appeals the final recommendations are issued as NICE guidance. The technology appraisal is published on the NICE website and incorporated into NICE Pathways.

Fast Track Appraisal (FTA)

- A new process, used for technologies that offer exceptional value for money to provide quicker access for patients to the most cost-effective new treatments.
- Broadly follows STA process, but final guidance produced at Week 32.

Multiple Technology Appraisal (MTA)

- Assesses several drugs or treatments used for one condition
- Also used if a new topic for an appraisal is particularly complex and not suited for the single technology appraisal process. It's also used for reviews of published appraisals.

Week 0	Week 8	Week 14	Week 15	Week 16
NICE invite stakeholders to take part in the appraisal and to nominate clinical, commissioning and patient experts. NICE ask consultees to submit any relevant information about the topic. UKCPA CLINICAL PHARMACY ASSOCIATION NICE add the remit, scope and a list of consultees and commentators to the website. The remit is the brief for the appraisal. The scope sets out what the technology appraisal will cover and the questions that need to be addressed.	**Stakeholder information meeting may be held** All consultees and commentators can send up to two representatives to the meeting. UKCPA CLINICAL PHARMACY ASSOCIATION	Deadline for the receipt of consultee submissions	**Evidence review begins** NICE send the consultee submissions to an independent academic centre (called the Assessment Group). They use the consultee submissions to help write the assessment report on the clinical and cost effectiveness of the technology(ies).	**Expert invitations** We invite the selected clinical, commissioning and patient experts to attend the appraisal committee. We ask them to submit a statement on the technology and how it should be used in the NHS in England. UKCPA CLINICAL PHARMACY ASSOCIATION

Week 28	Week 30	Week 31	Week 32	Week 34
Assessment Group report received by NICE	Assessment report sent to the consultees and commentators for comment UKCPA CLINICAL PHARMACY ASSOCIATION	Assessment report published on the NICE website for information	Deadline for receipt of the expert statements UKCPA CLINICAL PHARMACY ASSOCIATION	Deadline for the consultee and commentator comments on the assessment report UKCPA CLINICAL PHARMACY ASSOCIATION

Week 36	Week 37	Week 40	Week 41	Week 42
Key documents sent to the appraisal committee The appraisal committee is an independent advisory committee that makes the recommendations.	NICE hold an appraisal committee meeting to consider the committee papers and hear from nominated clinical, patient and NHS commissioning experts. The committee will decide to develop an appraisal consultation document (ACD) or final appraisal determination (FAD). UKCPA CLINICAL PHARMACY ASSOCIATION The ACD contains the draft recommendations from the Appraisal Committee and is produced when the recommendations from the Appraisal Committee don't recommend use of the technology, or limit the use of the technology beyond the specifications in the marketing authorisation. The FAD is the final draft of the guidance and includes the committee's final recommendations. If an ACD isn't needed NICE move straight to developing the Final Appraisal Determination (FAD) (see week 42).	**Appraisal consultation document (ACD) and supporting documents sent out for comment** Consultees and commentators have 20 working days to submit their comments on the draft recommendations. UKCPA CLINICAL PHARMACY ASSOCIATION	**Public consultation on the ACD** The ACD and supporting documents are published on the website for comment. Anyone can submit comments during consultation.	**Final appraisal document (FAD) sent to consultees and commentators for comment (if no ACD produced)** Consultees have 15 days to appeal. UKCPA CLINICAL PHARMACY ASSOCIATION

Week 44	Week 45	Week 47	Week 51	Week 52
Public consultation on the ACD ends	**Appraisal committee meet to develop the FAD** The Appraisal Committee considers the comments received on the ACD, then makes its final recommendations on how the technology should be used in the NHS in England. This is the FAD.	**Guidance issued (if no ACD)** If no ACD was produced and no appeals have been received, the topic is published. This is the earliest possible point that final guidance can be issued.	**FAD and supporting documents sent to consultees and commentators** Consultees have 15 days to appeal against the final recommendations in the FAD. UKCPA CLINICAL PHARMACY ASSOCIATION	**FAD published** We publish the FAD and supporting documents on the website for information.

Week 54	Week 60
Close of appeal period If no appeals have been received, the guidance is prepared for publication. If appeals have been received, the appeals process is followed.	**Technology appraisal published** If there are no appeals the final recommendations are issued as NICE guidance. The technology appraisal is published on the NICE website and incorporated into NICE Pathways.

Clinical guideline development

- NICE guidelines are based on the best available evidence.
- NICE recommendations are put together by experts, people using services, carers and the public.
- The development time for guidelines is usually between 12 and 27 months (from the start of scoping to publication), depending on the size and scope of the topic.

Stage 1	Stage 2	Stage 3	Stage 4
Topics are referred to NICE from the following organisations: • Healthcare topics: NHS England • Public health topics: Department of Health • Social care topics: Department of Health and Department for Education A number of factors influence the guidelines that NICE develops and the order of development.	**Scope produced** The scope outlines: • why there is a need for the guideline • the areas the guideline will and will not cover • what it intends to achieve. A draft scope is provided to organisations with an interest in the topic to comment on. Following this, a final version of the scope is published. UKCPA CLINICAL PHARMACY ASSOCIATION	**Guideline developed** • NICE review the evidence relevant to the guideline. This is developed by agreeing on review questions. Review questions help define literature searches, inform the planning and process of the evidence review, and act as a guide for the development of the recommendations. • The evidence is considered by a committee made-up of practitioners, professionals, care providers, commissioners, those who use services and family members or carers. UKCPA CLINICAL PHARMACY ASSOCIATION	**Draft guideline sent for consultation** NICE send a draft version of the guideline to stakeholders. Equality issues are identified and considered before the guideline is sent out, and the guideline is assessed for its impact on equality. UKCPA CLINICAL PHARMACY ASSOCIATION

Stage 5	Stage 6	Stage 7
Comments considered, guideline revised The guideline developer considers comments from stakeholders and agrees any changes. The revised version is reviewed and checked for quality.	**Guideline signed off and published** The Guidance Executive considers the guideline and signs it off for publication.	**Updating guidelines** NICE guidelines are updated regularly and prioritised according to users' need for new and updated guidelines.