Advanced breast cancer: diagnosis and treatment (Partial update)

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Association of Breast Surgery			We feel this is an oncology topic and so we do not have any specific comments to make.	Thank you for responding to this consultation and for confirming that you have no specific comments.
AstraZeneca UK	1	15–20	The draft scope states that "biological therapy for advanced breast cancer" is not being covered by a separate review due to plans to incorporate relevant TA guidance. It is unclear which medicines fall within the "biological therapy" category as no definition of this is provided in the draft scope or surveillance review. Further information on what therapies NICE consider to be biological therapies should be included.	Thank you for your comments. The draft scope refers to the 'categories' of systemic disease modifying therapies under which recommendations are grouped in the original CG81 guideline. e.g. chemotherapy, biological therapy. This is to enable readers to identify which recommendations within the existing guideline are being referred to, and the related sections of the surveillance review In the existing guideline, there is currently only one recommendation in the category of 'biological therapies' (recommendation 1.3.12 on the use of trastuzumab). However, as part of the guideline update, all relevant NICE technology appraisals, many of which have been published since the guideline was published in 2009, will be incorporated into the guideline unchanged without any further review of the evidence. The interim process through which NICE technology appraisals will be incorporated is explained here. The incorporated technology appraisals will include those relating to targeted therapies and immunotherapies, which if placed under the existing

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				categories, would fall into the area of biological therapies. However, the layout of the updated guideline is still to be determined. The headings are expected to be different from the existing guideline. The terminology may also be updated. For the purposes of the scope and to enable readers to relate to it to the existing guideline, the term 'biological therapy' has been used.
AstraZeneca UK	5	2–3	The draft scope states that "technology appraisal guidance will be incorporated into the guideline where relevant". AstraZeneca UK welcomes the incorporation of relevant technology appraisal (TA) guidance into guidelines to ensure guidelines are up to date. However, it is not clear how TA guidance will be incorporated into the guideline, specifically how TAs will be identified for incorporation; it is unclear whether all TAs related to advanced breast cancer will be incorporated or just those related to	Thank you for your comments. We are planning to incorporate all of the relevant NICE technology appraisals into the updated guideline. This will apply to all sections of the updated guideline, not just those areas in which evidence is being reviewed. The interim process through which NICE technology appraisals will be incorporated is explained here.

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			topics identified for update in the draft scope or surveillance review. Further clarity on how and which TAs will be incorporated into the guideline should be provided.	
AstraZeneca UK	5; surveillance review, page 4	-	The draft scope and surveillance review for this topic highlight that some areas of the guidelines will be amended via content alignment (i.e., without an evidence review). This includes managing metastatic breast cancer in the brain (aligning with NICE's guideline on brain tumours [primary] and brain metastases in over 16s [NG99]) and endocrine therapy for advanced breast cancer (aligning with TA guidance on CDK4/6 inhibitors and TA496 specifically). AstraZeneca welcomes content alignment with other up to date NICE guidelines/guidance. However, AstraZeneca wishes to note the following points:	Thank you for your comments. All relevant NICE technology appraisals (TAs) will be incorporated unchanged into the updated guideline, without further review of the evidence underpinning them. This will include the technology appraisals relating to the CDK4/6 inhibitors. TA496 on ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer is just one example of this. The interim process through which NICE TAs will be incorporated is explained here. As part of the process of incorporating the TAs, the existing CG81 guideline may need to be restructured. We envisage that a similar structure (by receptor subtype) to the NICE guideline on Early and Locally advanced breast cancer (NG101) is likely to be used for the Systemic anti-cancer therapy section in the updated CG81 guideline, but

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			• It is unclear what updates will be made to align with TA guidance on CDK4/6 inhibitors in relation to endocrine therapy for advanced breast cancer, and the relevance of TA496 in particular (over TAs for other CDK4/6 inhibitors). Further clarity should be provided to outline the planned changes. AstraZeneca encourages NICE to consider whether further updates are required to recommendations on managing metastatic breast cancer in the brain, in addition to content alignment with NG99 (last updated in January 2021), such as guidance on specific systemic anti-cancer therapies with proven efficacy in brain.	this is subject to discussion with the committee. Some of the existing CG81 guideline recommendations may be replaced by the TAs, or they may require editorial amendment. If that is the case, these will be discussed by the guideline committee as part of the update process. We have already incorporated TAs into the NICE guideline on Early and Locally advanced breast cancer (NG101). The format of the incorporated TAs in CG81 is also expected to be very similar to the NG101 guideline. See the sections on Triple Negative Breast Cancer and Locally advanced inoperable disease in NG101 for examples of TA incorporation. Regarding brain metastases, where there are systemic therapies with TAs that are indicated for the treatment of metastases to the brain as a result of breast cancer, they will be incorporated in the update of this guideline on advanced breast cancer. We are not planning to look specifically at systemic anti-cancer therapies with proven efficacy in brain as

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				part of the current update because these therapies would come under the scope of the NICE guideline on Brain tumours (primary) and brain metastases in over 16s (NG99) rather than this guideline (CG81). TAs relating to brain metastases will be incorporated into the NICE guideline on Brain tumours (primary) and brain metastases in over 16s (NG99) when that is updated as part of NICE's ongoing process of incorporating technology appraisals into guidelines.
Breast Cancer Now	1	15-19	**Re: Biological therapy for advanced breast cancer** We note that NICE do not intend to review evidence into biological therapy for advanced breast cancer as part of this guideline update, due to plans to incorporate relevant NICE technology appraisals into the guidance. We appreciate that an evidence review may not be appropriate here. However, due to the complexity of biological therapy pathways for advanced breast cancer, we would	Thank you for your comments. As registered stakeholders, Breast Cancer Now will have the opportunity to comment on the draft guideline at consultation. The interim process for incorporating the technology appraisals and the opportunities to provide feedback are explained here.

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			appreciate the opportunity to review how the information contained in technology appraisals will be presented when incorporated into the guidance. This will allow us to ensure that all treatment options are clearly and appropriately presented.	
Breast Cancer Now	5	1	**Re: Proposed outline for the guideline – Diagnosis and assessment** We disagree with the very limited scope presented for the update of guidance on diagnosis and assessment. We believe the guideline should be updated to recommend that patients with advanced breast cancer have their treatment and care managed by a multidisciplinary team. An MDT is considered the 'gold standard' in planning treatment and care for patients living with advanced breast cancer. However, we know that many MDT meetings do not	Thank you for your comments. There is existing NICE guidance which makes recommendations about multi-disciplinary team involvement for people with metastatic breast cancer – see Chapter 8 of CSG1 Improving outcomes in breast cancer. The evidence in this area won't therefore be reviewed as part of this update. We are aware that there is variation in practice in terms of how this is implemented however, as is noted in section 2.2 of the Equalities and Health Inequalities Impact Assessment. We will therefore consider how best to signpost readers from the updated guideline to the existing recommendation in guideline CSG1 and to the NICE quality standard QS12 on Breast Cancer which as you note, covers this area.

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			specifically discuss advanced cancers and often do not discuss people with advanced breast cancer at all. MDT discussion of people with advanced breast cancer is currently supported by other guidelines, standards, and strategies, including: The NICE Breast Cancer Quality Standard the International consensus guidelines for the management of advanced breast cancer (ABC 6 &7), and the National Audit of Metastatic Breast Cancer's Quality Improvement Plan. It is appropriate that this issue be included in the scope so that guidance can be aligned.	
Breast Cancer Now	5	1	**Re: Providing information and support for decision making** We believe that further updates are required to this section of the guidance, and recommend that it be included in the scope.	Thank you for your comments. We recognise the important role of Cancer Nurse Specialists for all people with cancer including for those with metastatic breast cancer. We are also aware that there is variation in access to this specialist support and this has been reflected in section 2.2 of the

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			There is currently no recommendation in the guideline addressing the need for people with advanced breast cancer to have access to a Clinical Nurse Specialist (CNS) with the right skills and experience, as well as the dedicated time, to support them throughout all stages of their disease, despite this being a key recommendation in both the Cancer Strategy published in 2015 and the NHS Long Term Plan. We believe the current recommendation relating to a 'key worker' (in section 1.4.1) does not adequately reflect the level of care and expertise that should be provided. CNSs play a crucial role in coordinating care and providing the information and support people need to manage their diagnosis and treatment. Access to a CNS is particularly important for people with advanced breast cancer who will be	Equalities and Health Inequalities Impact Assessment. The scope lays out the areas in which evidence will be reviewed. We do not plan to review the evidence in this area but will consider how best to signpost readers from the updated guideline to the NICE Quality standard QS 12 breast cancer. This includes statement 6, which specifies that 'People with locally advanced, metastatic or distant recurrent breast cancer are assigned a key worker.' It notes in the later text that 'People with locally advanced, metastatic or distant recurrent breast cancer have a healthcare professional (often a nurse who specialises in breast cancer) assigned to them as their key worker. The key worker gives information and support throughout the person's care'.

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			on lifelong treatment and often have very complex emotional and supportive care needs. However, Breast Cancer Now's research found that only 73% of respondents were given the name of a CNS at diagnosis. If patients are assigned a CNS, regular contact is problematic: only 30% of respondents said they see a CNS regularly, and those who said they do have one received much better support. In comparison, as shown in the results of the National Cancer Patient Experience Survey, we know that the overall percentage of patients with a diagnosis of breast cancer that are given the name of a specialist nurse is higher. With progress in research and treatments, more people are living longer after a diagnosis of advanced	

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			breast cancer. This positive progress must be matched by a change in how we assess and meet the needs of these patients, including ensuring that they have good access to a CNS to support them to live well.	
Breast Cancer Now	6	6	**Re: people with suspected advanced breast cancer** We strongly disagree with the decision that the guideline should not include recommendations on identifying people in primary care with suspected advanced breast cancer and referring them to secondary care. There is currently a gap between NG101 Early and locally advanced breast cancer: diagnosis and management and this guideline, which means there is a lack of guidance on the prompt identification and referral of these patients. NG12 Suspected cancer: recognition and referral also does not cover these patients as it focuses on primary cancers only.	Thank you for your comments and for raising this issue. The points you raise about lack of information regarding, and awareness of, the possible signs and symptoms of advanced breast cancer is included in section 2.2 of the Equalities and Health Impact Assessment. This notes that there may be a lack of awareness among both patients and health professionals of the signs and symptoms to look out for. While the initial identification and referral of people with advanced breast cancer is out of scope of the CG81 guideline, we are aware that there is a gap in NICE guidance. As you note, the NICE guideline NG12 focuses on the signs and symptoms of a range of primary cancers and doesn't cover secondary cancers. We will raise this again with our surveillance team as an area to be aware of and

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			While a prompt diagnosis may not lead to a different clinical outcome for the patient, it's important that people are diagnosed quickly for a number of reasons, including: • starting treatment sooner with a view to lengthening periods of progression-free survival • accessing support to manage symptoms and improve their quality of life enabling them to live as well as possible with their disease • reducing the chances of serious complications from the cancer such as spinal cord compression We would like to highlight feedback we have made previously on this issue dating back to 2015, including repeatedly flagging this issue with the surveillance team. Guidance currently	would also encourage you to submit a topic suggestion through our topic prioritisation process. See here for information on the prioritisation process and the submission form: • Prioritising our guidance topics | NICE • Topic suggestion | Prioritising our guidance topics | Our guidance | What NICE does | NICE. The NICE guideline on Early and locally advanced breast cancer NG101 has a recommendation on follow up (1.15.4). We note your concerns that this could be more detailed and have made contact with you to determine whether the requested changes could be made editorially within our processes. In addition, we will highlight to our implementation team that health professionals may not be providing sufficient information on specific symptoms and signs that could indicate metastases.

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			provided in NG101 Early and locally advanced breast cancer: diagnosis and management is too vague, referring only to giving patients information on 'signs and symptoms to look out for and seek advice on' within a written care plan. We would like to see this updated to be clearer and specific about what healthcare professionals should inform patients of, i.e.: • The signs and symptoms to be aware of which could be indicative of advanced cancer • How and who to report any concerns to It is vital that guidance is improved in this area. Unfortunately, we know that many people with secondary breast cancer were not provided with this information when completing their treatment for primary breast cancer.	

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			Research by Breast Cancer Now in 2019 found that lack of awareness is a significant problem. Only 13% of survey respondents who had previously had breast cancer felt they were given enough information from healthcare professionals on the signs and symptoms of advanced breast cancer to look out for. In addition, the National Cancer Patient Experience Survey has, over a number of years, found that breast cancer patients are among those least likely to say they were given enough information about the possibility and signs of cancer coming back or spreading - the most recent survey found that only 58% of breast cancer patients said they were given enough information.	
Breast Cancer Now	8	4-9	We support the proposed review of guidance on platinum containing chemotherapy for people with	Thank you for your comments and confirming your support for the inclusion of this area in the update of the guideline.

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			advanced triple negative breast cancer and breast cancer of any receptor sub-type with a BRCA mutation. Updates may be needed on this topic to bring NICE guidance into line with international guidance.	
Breast Cancer Now	8	11-20	We also support the proposed review of FDG PET-CT for detection of distant metastases and monitoring response to treatment. Updates may be needed to bring NICE guidance into line with international guidance.	Thank you for your comments and confirming your support for the inclusion of this area in the update of the guideline.
British Nuclear Medicine Society	General	General	In terms of cost effectiveness: **Naghavi-Behzad M, Gerke O, Kodahl AR, et al. Cost-effectiveness of 2-[^{18}F]FDG-PET/CT versus CE-CT for response monitoring in patients with metastatic breast cancer: a register-based comparative study. *Sci Rep*. 2023;13(1):16315. Published 2023 Sep 28. doi:10.1038/s41598-023-43446-7**	Thank you for providing this information to support your comments. We will review this paper to determine whether it meets our inclusion criteria when we carry out the relevant evidence review.

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			showed FDG PET/CT to be more cost effective in follow up of patients with oligometastatic/ oestrogen receptor positive breast cancer.	
British Nuclear Medicine Society	General	General	In terms of FDG PET-CT improving outcomes compared with conventional imaging: **Cochet, A., David, S., Moodie, K., Drummond, E., Dutu, G., MacManus, M., Chua, B. and Hicks, R.J., 2014. The utility of 18 F-FDG PET/CT for suspected recurrent breast cancer: impact and prognostic stratification. *Cancer Imaging*, *14*, pp.1-9** showed PET-CT had an impact in therapeutic management in 57% of patients both in terms of detecting disease not found on conventional imaging but also having a better negative predictive value therefore patients did not require a change in management. This study also showed a strong link between PET status and survival (systemic disease	Thank you for providing this information to support your comments. We will review this paper to determine whether it meets our inclusion criteria when we carry out the relevant evidence review.

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			according to PET/CT had a 4.7-fold in the risk of death when compared with patients with negative PET/CT findings, while patients with only loco-regional recurrence had a 2-fold increase in the risk of death)	
British Nuclear Medicine Society	8	11	NICE should review the role of FDG PET/CT from both a clinical perspective with a view to improving outcomes, reducing numbers of scans patients may need thereby reducing overall radiation burden and also from cost/resource perspective and as such welcome this review. Use of FDG PET-CT in imaging of breast cancer (BC). Studies have shown the added value of FDG PET-CT in imaging of BC and its advantages over conventional contrast enhanced CT +/- bone scan in the detection of nodal and distant disease at diagnosis. Literature shows a better diagnostic accuracy of	Thank you for your comments and the information provided in support of the inclusion of this area in the update of the guideline.

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			FDG PET-CT to detect distant metastases compared to the combination of conventional imaging, due to its higher sensitivity (97–99% vs 56–75%) and specificity (95–99% vs 88–99% It is acknowledged that FDG PET-CT has a more limited role in imaging invasive lobular BC Evidence-based indications for the use of PET-CT in the United Kingdom 2022 by RCP/RCR supports the use of FDG PET-CT in BC as a problem solving tool where there are equivocal findings on conventional imaging but also suggests using FDG PET-CT to replace contrast enhanced CT and bone scan in patients with locally advanced BC or those patients at high risk of nodal or distant disease EANM-SNMMI guidelines: STAGING	

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			- Not recommended in Stage I cancers - May be useful in clinical stage IIA (T1N1 or T2N0), but there is not enough - data - Recommended in baseline staging of stage IIB (preferably before surgery) and stage III (including inflammatory BC) - FDG PET/CT can be done instead of, and not in combination with, conventional imaging modalities for staging - Baseline treatment planning may improve RT planning - Stage IV - Can be useful for determining the extent of metastatic disease (outside the brain) and improving treatment planning - FDG PET/CT can be done instead of, and not in addition	

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			to separate conventional imaging modalities RESPONSE ASSESSMENT - Non metastatic BC to assess early metabolic response (esp TNBC and HER2+) - Metastatic BC – may play role in treatment response; esp bone metastases RECURRENCE - Useful to detect the site and extent of recurrence when conventional imaging methods are equivocal - In patients with signs or symptoms suggestive of metastatic disease - In patients with rising serum tumour markers - To guide the site of biopsy - To improve RT planning - Can substitute CT and/or bone scan in the detection of bone metastases	

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			Vaz SC, Woll JPP, Cardoso F, et al. Joint EANM-SNMMI guideline on the role of 2-[18F]FDG PET/CT in no special type breast cancer : (endorsed by the ACR, ESSO, ESTRO, EUSOBI/ESR, and EUSOMA). Eur J Nucl Med Mol Imaging. 2024;51(9):2706-2732. doi:10.1007/s00259-024-06696-9	
Can-Survive UK	03	19	The draft scope currently excludes people aged 18 and above with benign breast conditions. We feel this group should be included because those conditions can become cancerous if abnormal cells continue to grow.	Thank you for your comment. People with breast conditions which are benign at diagnosis are excluded from the scope of the CG81 guideline as it focuses on people with advanced breast cancer (defined as invasive adenocarcinoma of the breast with distant metastases). Where someone has a benign breast condition which does ultimately become cancerous, they would be included within the scope of NICE guideline NG101 on early and locally advanced breast cancer: diagnosis and management, or the scope for CG81: advanced breast cancer, depending on the stage of the cancer. The NICE guideline on suspected cancer (NG12) covers recognition and referral of people

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				with suspected cancer and people with benign breast conditions would be covered by this guideline should they develop any symptoms of breast cancer.
Can-Survive UK	06	8	Currently, the draft scope excludes the management of breast cancer and related risks in people with family history of breast cancer. We feel this is an important aspect that should not be overlooked as it will play a vital role in early detection which will in turn improve health outcomes of the community we serve.	Thank you for your comments. The management of breast cancer and related risks in people with a family history of breast cancer is excluded from the scope of the update of this guideline on advanced breast cancer, This is because this area is covered by NICE guideline CG164. CG164 focuses specifically on familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer. This guideline is currently being updated.
METUPUK	1	8	Patient groups were not included in the discussion during the initial scoping process. This means that the patient voice was not heard at the beginning of the guideline development. CG81 as it is now bears no resemblance to current treatment of MBC in the NHS and in our experience this causes concern for patients, particularly the newly	Thank you for your comments and for responding to this consultation. Development of the draft scope and consultation with registered stakeholders is the first step in the guideline development process. A stakeholder workshop was not held for this guideline update because it is a small update based on a detailed surveillance report. However around half the comments received at consultation were from organisations representing patients. The committee which will develop the guideline has not yet been

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			diagnosed. Patients who have been diagnosed for longer perceive CG81 as irrelevant. A guideline should be neither concerning or irrelevant. In CG81(pp12-14) some areas for further research are identified. Had patient groups been invited to a scoping workshop, we would have asked how much of this research has been done, and how much remains unanswered. For example, for exercise, we are aware of variations between Trusts in provision of cancer rehab and so uncertainty in the research translates into variations in care. For trastuzumab beyond progression, we are pleased that there are now four HER2-directed treatment lines available, but for patients going into fifth line and beyond trastuzumab is not offered in standard NHS care. It is offered in many clinical trials to reflect international standard of care.	recruited but will include several members representing people who have experience of living with metastatic breast cancer. There will be a stakeholder consultation on the draft guideline and the views of groups representing patients will be an important and welcome part of that process. We agree that the guideline needs updating and plans to incorporate all relevant NICE technology appraisals will be a key element in bringing the guideline into line with current clinical practice. Regarding the research recommendations in CG81, the incorporation of the relevant NICE technology appraisals will supersede the need to review some of these areas, for example those on the systemic therapies. As part of the update we will also ask the committee whether any other of the existing recommendations have been addressed by research and only those that remain relevant will be retained. Regarding the research recommendation on exercise in relation to lymphoedema, please note

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				that this has recently been updated for all people with breast cancer (both early and locally advanced breast cancer and advanced breast cancer). The recommendations are included in the NICE guideline on Early and locally advanced breast cancer (NG101) and cross referred to from CG81. Regarding trastuzumab beyond progression, we are aware that there is variation in practice. However, this is not an area in which evidence will be reviewed as part of the guideline update. Instead, relevant NICE technology appraisals, including those on trastuzumab, will be incorporated unchanged into the guideline as part of the update process. The interim process for incorporating the TAs and the reasons for doing so, are described here.
METUPUK	1	15	We understand and welcome that NICE are now updating guidelines using a modular approach, and that Technology Appraisals are to be incorporated into guidelines. We hope that HTAs will be referenced in relevant sections (ideally with	Thank you for your comments. All relevant NICE technology appraisals will be incorporated into the updated guideline. The interim process for incorporating the TAs and the reasons for doing so, are described here. We agree that this will be an important factor in reflecting current clinical practice.

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			weblinks to the appropriate page on the NICE website) so the guideline resembles current treatment pathways, rather than best practice in 2009. It is important the incorporation of technology appraisals is explicitly documented in the guideline to make the guidance easier to navigate.	
METUPUK	2	1	Agree use of platinum chemotherapy needs a full evidence review because no HTA has been carried out.	Thank you for your comments and support for the inclusion of this area in the guideline update.
METUPUK	2	9	Agree, patients report inconsistencies in the use of ^{18}F-FDG PET-CT scans for diagnosis and monitoring of treatment response across the country. Research is needed to identify reasons for disparities. It is noted the UK has the lowest number of PET-CT scanners per million population amongst comparator countries (at 0.5 per million in 2021). https://www.gov.uk/government/publications/life-sciences-sector-data-	Thank you for your comments and this information. The points you raise about the potential distance some people may need to travel to attend scanning appointments and the associated travel costs have been added to section 3.2 of the post-scope consultation version of the Equalities and health inequalities impact assessment.

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			2024/life-sciences-competitiveness-indicators-2024-summary [Accessed 25 November 2024]. If PET-CT scans cannot be carried out close to patient homes because of shortage of scanning centres, cost of travel and length of travelling time could be a barrier to access for some patients. Examples include the disabled, the elderly, people living in poverty or people living in rural areas. It is important to address inequalities and ensure no groups are disadvantaged.	
METUPUK	2	9	Research indicates that the diagnosis and monitoring of inflammatory breast cancer by PET-CT is of particular value. Please can the guideline committee consider the distinct needs of IBC patients. van Uden, DJP et al (2020) [18F]FDG PET/CT in the staging of inflammatory breast cancer: A systematic	Thank you for your comments and the link to this paper. As inflammatory breast cancer is an epithelial adenocarcinoma, it is included within the scope of the guideline once it is has become metastatic. We will discuss with the committee whether to include inflammatory breast cancer as a separate population of interest for our analyses when we develop the review protocols.

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			review. *Critical Reviews in Oncology/Hematology* Vol 151, July 2020, 102943 available at: https://www.sciencedirect.com/science/article/abs/pii/S1040842820300810 [Accessed 22 November 2024].	
METUPUK	2	9	We also would like to understand if any groups of patients are likely to be disadvantaged by being scanned by PET-CT. For example, patients with breast cancer that has a low FDG uptake. Would these patients benefit more from other scanning modalities?	Thank you for your comments. The committee have advised us that the NHS uses FDG as standard and that although other tracers are in development, there is still a limited evidence base for them, and they are not in widespread use. We therefore plan to limit our review to looking at FDG PET-CT. However, we will discuss with the committee whether we need to make separate recommendations for certain groups of people, such as people with breast cancer that has a low FDG uptake, to ensure that they are not disadvantaged by any recommendations that we might make in favour of using FDG PET-CT. Our review is also looking at the effectiveness of CT for diagnosing distant metastases and it might be the case that this is a better imaging modality for these people.

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METUPUK	2	9	Insufficient numbers of skilled staff in radiology, radiography and nuclear medicine are a barrier. Radiotracer availability is also a barrier. With a short half life, logistics of getting the isotopes to PET-CT sites can be challenging and if a cyclotron is down, then patients can have their scan cancelled at very short notice. This has been experienced by members of our patient group and is distressing for patients and difficult for staff who have to deal with rescheduling appointments. It is also a waste of NHS resources to have scanning equipment idle. https://society-of-radiographers.shorthandstories.com/the-growth-and-progression-of-pet-ct/ [Accessed 25 November 2024]	Thank you for your comments. While taking implementation issues into account, the committee will make recommendations on the basis of effectiveness and cost effectiveness to reflect best practice. However, we will endeavour to provide alternative options for imaging, where possible, to address issues such as the ones you mention here, and in your comment above about the limited availability of PET-CT scanners. We will liaise with NICE colleagues specialising in resource impact and implementation regarding these issues, but please note that NICE cannot control the local commissioning of services.
NHS England	General	General	We strongly suggest the document makes reference to making reasonable adjustments. This is a	Thank you for your comments. The points you raise about making reasonable adjustments and making reference to the Reasonable Adjustment Digital Flag

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			legal requirement as stated in the Equality Act 2010. Adjustments aim to remove barriers, do things in a different way, or to provide something additional to enable a person to receive the assessment and treatment they need. Possible examples include allocating a clinician by gender, taking blood samples by thumb prick rather than needle, providing a quiet space to see the patient away from excess noise and activity. We recommend including reference to the Reasonable Adjustment Digital Flag (RADF) and the RADF Information Standard which mandates all providers and commissioners of health services and publicly funded social care to identify, record, flag, share, meet and review Reasonable Adjustments, including details of their underlying conditions.	(RADF) and the RADF Information Standard have been added to section 3.2 of the updated Equality and Health Inequalities Assessment, which accompanies the scope. There is a cross reference to this document from within the scope that will be hyperlinked on publication. In addition, the NICE guideline on Patient experience in adult NHS services includes recommendations about knowing the patient as an individual that cover taking the requirements of the Equality Act 2010 into account and making sure NHS services are equally accessible and supportive for everyone using them. The updated advanced breast cancer guideline will include cross reference to this guideline.
NHS England	General	General	We recommend including reference to the importance of Communication: Using simple, clear language,	Thank you for your comments. The Equality and Health Inequalities Assessment (EHIA) published alongside the draft scope for consultation, discusses

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			avoiding medical terms and 'jargon' wherever possible. Some people may be non-verbal and unable to describe verbally how they feel. Pictures may be a useful way of communicating with some people, but not all.	the importance of communication under the protected characteristic 'disability'. The EHIA also includes a hyperlink in section 2.3 to NHS England's Accessible Information Standard. This highlights the importance of identifying communication support needs and under 'Different types of accessible information and who may need them' notes that some people may use non-verbal communication and may be more likely to communicate in non-traditional ways. Your comments have also been reflected in section 3.2 of the updated EHIA. In addition, the updated advanced breast cancer guideline will include cross reference to the NICE guideline on Patient experience in adult NHS services. This contains a section with recommendations about enabling patients to actively participate in their care that covers communication. One of the recommendations in this section (1.5.4) covers establishing the most effective way of communicating with each patient and has a list of examples of how this could be done that includes pictures, symbols, involving a patient advocate and other approaches. It also contains a section with

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				recommendations about knowing the patient as an individual. The updated advanced breast cancer guideline will also cross refer to the NICE guideline on Shared decision making to facilitate this process.
NHS Wales Cancer Network	General	General	I've seen the scope of the guideline and unless I am missing some key links, I cannot see anything under imaging other than the plan, which I agree to in essence, but it focuses specifically on looking at the recommendations for CT PET in diagnosis and follow up which certainly needs to be updated.	Thank you for your comments. The guideline will be undergoing a partial update. The scope focuses only on areas in which evidence will be reviewed and recommendations updated, or new recommendations made. In the final scope you will see the draft questions focus on comparing the diagnostic accuracy and cost of PET-CT, or CT with and without bone scintigraphy for the diagnosis of metastases, and on PET-CT for monitoring response to treatment. Where the evidence underpinning an existing recommendation is not being reviewed, the recommendation in the current guideline will be retained and included in the updated guideline.
NHS Wales Cancer Network	General	General	My concern here is who is sitting on the panel and reviewing the evidence in terms of what is available in different regions and how the final	Thank you for your comments. We agree it will be important to develop robust evidence-based recommendations for baseline imaging and for follow-up. The committee will be multi-disciplinary

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			guidance will affect us in terms of early diagnosis and timely follow up. We need to ensure there are robust recommendations for baseline imaging and ease of access to follow up imaging. ……..[redacted text]..I very much feel we will be doing a disservice to our patients if on this rewrite, someone experienced in secondary breast cancer but also value based healthcare is not representing radiology in Wales.	and will include radiologists with relevant experience in this area. Positions on the committee are open to suitable candidates from Wales and elsewhere in the UK, but we will be limited to appointing committee from the group of people who apply.
The Faculty of Pharmaceutical Medicine	5	1.5	Add the need for awareness of the significant rise in secondary malignancies for patients, especially those with homologous recombination deficiency-positive disease.	Thank you for your comments. This issue is not currently covered by the scope of this piece of work. However, if you have evidence to support its inclusion in future work please can you share it with us by submitting a topic suggestion through our topic prioritisation process. See here for information on the prioritisation process and the submission form: • Prioritising our guidance topics • Topic suggestion.

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The Institute of Cancer Research	1	20-22	Not clear from this statement if the two areas below are or are not "in scope" because they will be reviewed elsewhere and incorporated in the breast cancer guideline update through another process. They are important areas where multiple pieces of evidence have recently been published that should in some process or other be reviewed and contribute to an update in guidance. • Biological therapy for advanced breast cancer and • Ovarian function suppression for premenopausal and perimenopausal women with oestrogen receptor-positive advanced breast cancer.	Thank you for your comments. The evidence in these areas will not be reviewed as part of this update. As part of this update, all relevant NICE technology appraisals (TAs), will be incorporated into the guideline. This includes TAs on biological therapies and on drugs such as the CDK4/6 inhibitors, some of which are given with aromatase inhibitors. As the relevant treatments are covered by TAs, the TA incorporation process will be used to update these sections rather than carrying out an evidence review. The interim process for incorporating the TAs and the reasons for doing so, is described here.
The Institute of Cancer Research	4	6-9	The reference to "BRCA germline mutation" should be extended to cover germline mutations in PALB2 and also cover "somatic" in BRCA1, BRCA2 and PALB2 and mutations identified in	Thank you for your comments and references. Regarding extending the review on platinum-containing chemotherapy regimens to include people with PALB2 germline mutations and somatic BRCA1, BRCA2 and PALB2 mutations, this was

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			tumour by panel or whole genome sequencing (NHSE funded sequencing in GLHs). It would also be important to review evidence for use of PARP inhibitors patients with all receptor subtypes of advanced breast cancer with BRCA1, BRCA2 and PALB2 and mutations identified in germline and or in tumour. There are multiple studies that identify activity in patients with these mutations including but not limited to PMID: 36071165 PMID: 33119476 https://ascopubs.org/doi/10.1200/JCO.2024.42.16_suppl.1021 PMID: 29713086 https://ascopubs.org/doi/10.1200/PO.17.00258, https://pmc.ncbi.nlm.nih.gov/articles/PMC10444947/	discussed during scoping, however there were concerns about there being a lack of higher-level evidence from randomised controlled trials on PALB2 germline mutations to form the basis for making recommendations. In addition, somatic BRCA and PALB2 mutations are not, at present routinely screened for in NHS practice. We are aware of increasing research on tumour mutation testing and will flag this to our surveillance team. We have therefore continued to focus on BRCA germline mutations for this question. Regarding PARP inhibitors, the evidence in these areas will not be reviewed as part of this update. This is because as part of the update, all relevant NICE technology appraisals (TAs), including those on PARP inhibitors for people with BRCA germline mutations (TA1040), will be incorporated into the guideline.
THE UK CHARITY for TRIPLE	1	E & HE	The problems of collecting numbers of patients with MBC are highlighted but not the importance of collecting	Thank you for your comments. The importance of collecting data on the major phenotypes of breast cancer has been added to the updated Equalities

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NEGATIVE BREAST CANCER			information around the major molecular phenotypes, specifically TNBC because of it's definition.	and Health Inequalities Impact Assessment in section 3.2.
THE UK CHARITY for TRIPLE NEGATIVE BREAST CANCER	2	E&HE	It is more accurate to say 'TNBC is more likely than the other common types of breast cancer to affect women of child bearing age'	Thank you for your comment and for clarifying this point. This has been noted for future reference, however the EHIA is an iterative document and so the text published at consultation cannot be amended retrospectively.
THE UK CHARITY for TRIPLE NEGATIVE BREAST CANCER	3	E&HE	The UK Charity for Triple Negative Breast Cancer is also a registered stakeholder.	Thank you for your comments and for registering as a stakeholder. In section 3.1 of the post scope consultation EHIA, organisations that responded to the consultation that represent people who may experience inequalities relating to this topic have been added, including The UK Charity for Triple Negative Breast Cancer.
THE UK CHARITY for TRIPLE NEGATIVE BREAST CANCER	8	2.5	The definition of Triple Negative Breast Cancer is sub optimal	Thank you for your comment. In section 1 of the draft scope, we have amended the definition of triple negative breast cancer to say: 'a type of breast cancer in which the cells do not express, or express at very low levels, receptors for oestrogen and progesterone, and do not overexpress receptors for human epidermal growth factor 2'.

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				Section 3.5 of the scope outlines a draft review question which refers only to 'triple negative breast cancer' without further definition, as it has been defined earlier in the document. In the review protocols that will set the parameters for each evidence review, the draft review question will be further refined and the included population will be specified in more detail.
THE UK CHARITY for TRIPLE NEGATIVE BREAST CANCER	8	2.5	There needs to be clarity whether those with ER-ve, PR unknown HER2-ve, are included in the definition of TNBC	Thank you for your comment. The NICE guideline NG101 on early and locally advanced breast cancer recommends that the ER, PR and HER2 status of all invasive adenocarcinomas are simultaneously assessed at the time of initial histopathological diagnosis (see section 1.3 on Assessment of tumour profile and genetic testing). Recommendation 1.3.3 specifically addresses the assessment of PR status and recommendation 1.3.5 notes that the status of all receptors is available and recorded at pre- and post-operative multi-disciplinary team meetings when systemic treatment is discussed. It is therefore likely that the PR status will be known for people who have previously had early or locally advanced breast cancer before developing metastases.

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				However, people who develop de novo metastatic disease or who have inconclusive test results may have unknown PR status. The level of detail of whether TNBC includes those with PR unknown status is more than we include in the scope, but we will discuss this issue with the committee when we develop the review protocol, review the evidence and draft recommendations on platinum-based chemotherapy.