Advanced breast cancer: diagnosis and management (Partial update)

Consultation on draft guideline - Stakeholder comments table
03/03/26 to 23/03/26

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Association of Breast Surgery	Guideline	004	015	Rather than linking to another document it would be much clearer to state the guidance and then link to the other guidance Individuals will be using this document to work out how to image and investigate these patients and having clear guidance will aid that.	Thank you for your comment. We have not looked at any evidence relating to the diagnosis of brain metastases because this is out of scope of this update and is covered by another NICE guideline. We accept your point about reducing clicks to access information. However, NICE takes the approach of avoiding repetition across guidelines by utilising links. This also allows for simpler updating of information at a single location when required. A new content management system is being developed that will hopefully make these cross references more user friendly in the future.
Association of Breast Surgery	Guideline	004	019	As above, state the guidance and then link to the other document.	Thank you for your comment. We have not looked at any evidence relating to the diagnosis of brain metastases because this is out of scope of this update and is covered by another NICE guideline. We accept your point about reducing clicks to access information. However, NICE takes the approach of avoiding repetition across guidelines by utilising links. This also allows for simpler updating of information at a single location when required. A new content

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					management system is being developed that will hopefully make these cross references more user friendly in the future.
Association of Breast Surgery	Guideline	015	001	I agree that more research should be done to work out the best treatments for locally advancing but stable distant disease and the role of different modalities to manage that. Although you state that this is a rare problem, my experience is that with the increasing systemic options there are a small but none the less not insignificant group whose local disease progresses despite otherwise good control. Whether surgery +/- radiotherapy, radiotherapy or a switch of systemic treatment is the best approach is not at this point clear.	Thank you for your comment. The research recommendation on uncontrolled local disease was not within the scope of this update and was greyed out at consultation to reflect this. The committee for this update agreed that this area remained important and retained this research recommendation to reflect this. The aim of the research recommendation to generate new evidence should hopefully address the lack of clarity you mention.
Association of Breast Surgery	Guideline	016	001	I agree there needs to be more work on the best imaging for ILC and this is a good context to set that work up.	Thank you for your comment and support for this research recommendation.
AstraZeneca UK	Guideline	005	015	We would like to propose adding a reference to the National Genomics Test Directory similarly to NG122, to guide the reader to further details on testing for genomic alterations, as there are now several SACTs which require a confirmed mutation prior to initiating targeted treatment. Proposed text: *"See the National Genomics Test Directory for guidance on next-generation sequencing (NGS) panels to guide treatment."*	Thank you for your comment. Genomics and genetic testing were not part of the scope of this update. As they were not assessed, no specific recommendations about types of tests could be made. However, the committee agreed that the guideline should signpost to the National Genomics Test Directory and so a new recommendation was added to do this. They also included a cross reference to the NICE

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					guideline on Familial Breast cancer (CG164) that is currently being updated.
AstraZeneca UK	Guideline	006	020	Olaparib and talazoparib: the draft guideline specifies prior anthracycline and a taxane are required but does not mention the requirement for endocrine therapy in the case of HR+ breast cancer. Adding this clarification would help align the guideline and the technology appraisal guidance document. In addition, the technology appraisal guidance for these two medicines state that the chemotherapy and endocrine therapy requirements are only applicable in patients who are suitable to receive those. We'd like this clarity to be provided to avoid undue confusion.	Thank you for your comment. We have included 'after endocrine therapy' in the later recommendation under the sub-heading Hormone-receptor-positive and HER2- negative advanced breast cancer, as below: For medicines recommended as options for treating HER2-negative, advanced breast cancer with germline BRCA1 or BRCA2 pathogenic variants after endocrine therapy or an anthracycline and a taxane, see NICE's technology appraisal guidance on: • olaparib (TA1040, 2025) • talazoparib (TA952, 2024)
AstraZeneca UK	Guideline	008	007	We would like to propose further alignment of disease status wording wherever possible: eg in 1.3.10 "Trastuzumab deruxtecan is recommended as an option for treating HER2-positive advanced breast cancer after 1 or more anti-HER2 treatments" however the technology appraisal title states "HER2-positive unresectable or metastatic breast cancer after 1 or more anti-HER2 treatments".	Thank you for your comment. To keep consistency with the guideline terminology we have used the terminology 'advanced breast cancer' as an all-encompassing term. We also advise the user to read the technology appraisal (TA) for further information, and the TA is hyperlinked within the recommendation.

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AstraZeneca UK	Guideline	012	014	We are unclear why the section on Neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumours comes after "Treatments not recommended". Moving this section higher up could improve the document flow.	Thank you for your comment. We have moved this recommendation so that it is located before the section on treatments not recommended. We have kept the specific technology appraisals (TAs) for breast cancer separate to the neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumour TA, so that there is a clear distinction between the two indications. This is consistent with other solid tumour guidelines.
Breast Cancer Now	Guideline	003	005	We agree with the inclusion in guidance of discussions around clinical trials and research. Access to clinical trials is very important to patients with metastatic breast cancer as it means they can potentially access new and innovative treatment options. We know that there are currently variations in access to clinical trials as a result of a lack of knowledge, awareness, and guidance to discuss trials. Supporting patients to take part could go some way to addressing this issue.	Thank you for your comment and support of this new recommendation. To emphasise the importance of having these conversations regularly, the committee amended the existing recommendation about discussing clinical trials to clarify that these discussions should happen throughout the treatment pathway. They also included a cross reference to this recommendation at the start of the section on systemic anticancer therapy.
Breast Cancer Now	Guideline	003	013	We agree with the decision to include FDG PET-CT into the guidelines as it has higher sensitivity when compared to normal CTs for detecting abnormalities. Accurate and timely diagnosis of the presence and extent of distant metastases is very important to patients, as it is vital to	Thank you for your comments. Evidence review B found moderate to very low certainty evidence that FDG PET-CT may have high sensitivity for diagnosing metastatic disease, and low to very low certainty evidence that CECT may have

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				determine the extent of spread and therefore treatment options. It is vital to ensure that the system has capacity to deliver imaging as set out in the new guidance. We also note here that the ESMO guidelines do not recommend FDG PET-CT as a first option, but it is included in guidance and may be used instead of CT and bone scans. FDG PET-CT should be included in the guidelines as an option, not as the default imaging type, as reflected in the ESMO guidelines.	moderate sensitivity. Low certainty evidence suggested both tests may have high specificity. There was no evidence identified for FDG PET-CT for monitoring response to treatment. The recommendation about monitoring was based on the experience of the committee and the health economic model which used the assumption that FDG PET-CT and CECT were likely to perform in a similar way for monitoring as they did for diagnosis. The committee noted the issues of FDG PET-CT availability, accessibility and the potential impact on equity as part of their initial discussions when they drafted the recommendations. To try to address this at that time they recommended CECT if FDG PET-CT is not suitable, is inaccessible or is unavailable. The committee agreed that their draft recommendations did not correspond to the ESMO guidance, but they were written based on the committee's experience and interpretation of the evidence they reviewed.

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					Although the economic analysis suggested that FDG PET-CT is highly likely to be cost effective compared with CECT, the committee considered that uncertainties in the evidence base (particularly for monitoring), along with stakeholder and committee concerns around availability, system capacity and potential inequities in access justified positioning the modalities as equivalent. They have therefore amended the recommendation to allow use of CECT or PET-CT for initial imaging, rather than making FDG PET-CT the preferred option. To aid the decision on when to use FDG PET-CT or CECT, they added additional factors, including availability and patient preference, to the recommendation on factors to take account of when deciding which scanning modality to use for diagnosis.
Breast Cancer Now	Guideline	005	007	We agree with the inclusion of using the same imaging to monitor response to treatment on the basis that patients should be able to access the same type of imaging that they received upon original diagnosis and staging, so that their cancer can be monitored and compared accurately.	Thank you for your comments. The committee noted the issues of FDG PET-CT availability, accessibility and the potential impact on equity as part of their initial discussions when they drafted the recommendations. To try to address

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				It is important to note that not every hospital has access to PET scanners. Making this the default imaging type may require patients to travel further for diagnostic and monitoring, which should be avoided.	this at that time they recommended CECT if FDG PET-CT is not suitable, is inaccessible or is unavailable. Although the economic analysis suggested that FDG PET-CT is highly likely to be cost effective compared with CECT, the committee considered that uncertainties in the evidence base (particularly for monitoring), along with stakeholder and committee concerns around availability, system capacity and potential inequities in access justified positioning the modalities as equivalent. They have therefore amended the recommendation to allow use of CECT or PET-CT for initial imaging, rather than making FDG PET-CT the preferred option. To aid the decision on when to use FDG PET-CT or CECT, they added additional factors, including availability and patient preference, to the recommendation on factors to take account of when deciding which scanning modality to use for diagnosis. For monitoring response to treatment, they decided to change the recommendation to a

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					weaker 'consider' recommendation for using the same scanning modality used for diagnosis to better reflect some of the uncertainties in the economic model.
Breast Cancer Now	Guideline	007	006	We agree with the decision to include platinum-based chemotherapy. The most important thing to patients is being able to choose a treatment that works best for them. The inclusion of additional treatments gives both patients and oncologists more choice.	Thank you for your comment and support of this recommendation.
Breast Cancer Now	Guideline	020	004	It is important to note that radiology faces workforce and capacity issues. The implementation of PET-CT for use in monitoring disease status in the future could further exacerbate existing issues. This could lead to longer waits for patients, including in delays to treatment decisions or changes, or unequal access to services where patients must wait for the availability of PET-CT.	Thank you for your comment. The committee noted the issues of FDG PET-CT availability, accessibility and the potential impact on equity as part of their initial discussions when they drafted the recommendations. To try to address this at that time they recommended CECT if FDG PET-CT is not suitable, is inaccessible or is unavailable. The section of the guideline on 'How the recommendations might affect practice' that accompanies the diagnostic and monitoring recommendations acknowledges that there would need to be an increase in the availability of radiologists to interpret the scans. Although the economic analysis suggested that FDG PET-CT is highly likely to be cost effective

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					compared with CECT, the committee considered that uncertainties in the evidence base (particularly for monitoring), along with stakeholder and committee concerns around availability, system capacity and potential inequities in access justified positioning the modalities as equivalent. They have therefore amended the recommendation to allow use of CECT or PET-CT for initial imaging, rather than making FDG PET-CT the preferred option. To aid the decision on when to use FDG PET-CT or CECT, they added additional factors, including availability and patient preference, to the recommendation on factors to take account of when deciding which scanning modality to use for diagnosis. For monitoring response to treatment, they decided to change the recommendation to a weaker 'consider' recommendation for using the same scanning modality used for diagnosis to better reflect some of the uncertainties in the economic model.
Breast Cancer Now	Guideline	021	008	We agree with the committee's decision to include platinum-based chemotherapy as a suitable option, noting	Thank you for your comment and support for the addition of platinum-based chemotherapy as an

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				that the risk of side effects is high but that patient choice is important. Patients would need to be fully informed of the side effects so that they can work with clinicians to make an informed decision on what form of treatment would be best for them.	option for people with advanced triple negative breast cancer. The committee included side effects in the recommendation about what factors to base decisions about systemic anticancer therapy (SACT) on, as they agreed that it is an important consideration. A separate recommendation about informing patients about the side effects of the treatments that are suitable for them was not made, as these types of discussions should be routinely done already. Section 1.4 in NICE's guideline on shared decision making covers how these discussions should take place for all types of situations.
British Society of Breast Radiology	Guideline	005	001	Rec 1.2.6 This makes reference to reassessment of HR and Her 2 status which we take to imply as rebiopsy of any tumour that is progressing or possibly additional tumour sites. Again this is not clearly spelt out and has implications on current practice, workforce and service provision. We would recommend a caveat to this.	Thank you for your comment. The wording in this recommendation was originally for people whose breast cancer has recurred, and it was amended to progressed as part of this update in order to clarify the language in the context of metastatic breast cancer. It was not intended to change the meaning of the recommendation. After discussion with the committee, it was decided to revert to the original wording (recurrence rather than progression). This

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					section of the guideline was not in scope for the current update, and we are therefore unable to make more extensive changes to the recommendation.
British Society of Breast Radiology	Guideline	016	001	We support the research recommendation to recognise lobular breast cancer as a distinct subtype in breast cancer which has a different disease and metastases course. We draw attention to the highlight call from NIHR - Invasive lobular carcinoma (lobular breast cancer) highlight notice | NIHR and reiterate that key research especially into the efficacy of FAPI and FES pet with recognition of possibly a different longer term monitoring pathway may be needed for this group. Economic evaluations in this area will also be tempered by limited availability and costs of FAPI and FES generation.	Thank you for your comment and support for this research recommendation. Your mention of FAPI PET-CT and FES PET-CT are consistent with what is included in the research recommendation and in line with the NIHR call for research – this is useful confirmation.
British Society of Breast Radiology	Guideline	019	004	Rec 1.2.3 and Rec 1.2.7 –The BSBR would again stress that CECT is the first line investigation and activity should not default to PET-CT as the first investigation as per the Royal College of Radiology 5th edition of breast imaging guidelines. Guidance on screening and symptomatic breast imaging, fifth edition | The Royal College of Radiologists. We recommend that a joint approach to setting defined criteria for staging be agreed. NG 101 last updated 14 April 2025 does not cover this either. The utility of imaging in breast cancer recurrence and inflammatory	Thank you for your comment. The committee agreed that their draft recommendations did not correspond to the Royal College of Radiology 5th edition of breast imaging guidelines, but they were written based on the committee's experience and interpretation of the evidence they reviewed. The committee noted the issues of FDG PET-CT availability, accessibility and the potential

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				breast cancer for example are not specified. Identification of who benefits the most from staging should be considered as part of a clinical and resource question.	impact on equity as part of their initial discussions when they drafted the recommendations. To try to address this at that time they recommended CECT if FDG PET-CT is not suitable, is inaccessible or is unavailable. Although the economic analysis suggested that FDG PET-CT is highly likely to be cost effective compared with CECT, the committee considered that uncertainties in the evidence base (particularly for monitoring), along with stakeholder and committee concerns around availability, system capacity and potential inequities in access justified positioning the modalities as equivalent. They have therefore amended the recommendation to allow use of CECT or PET-CT for initial imaging, rather than making FDG PET-CT the preferred option. To aid the decision on when to use FDG PET-CT or CECT, they added additional factors, including availability and patient preference, to the recommendation on factors to take account of when deciding which scanning modality to use for diagnosis.

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					For monitoring response to treatment, they decided to change the recommendation to a weaker 'consider' recommendation for using the same scanning modality used for diagnosis to better reflect some of the uncertainties in the economic model. We have not looked at any evidence relating to criteria for staging because they were out of scope of this update, which was focused specifically on the use of FDG PET-CT and CECT imaging. 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.
British Society of Breast Radiology	Guideline	General	General	Access to PET-CT has been noted in the report to be challenging. There is concern that introduction into guidelines will introduce inequality in staging of breast cancer	Thank you for your comment. The committee noted the issues of FDG PET-CT availability, accessibility and the potential impact on equity as part of their initial discussions when they drafted the recommendations. To try to address

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					this at that time they recommended CECT if FDG PET-CT is not suitable, is inaccessible or is unavailable. Although the economic analysis suggested that FDG PET-CT is highly likely to be cost effective compared with CECT, the committee considered that uncertainties in the evidence base (particularly for monitoring), along with stakeholder and committee concerns around availability, system capacity and potential inequities in access justified positioning the modalities as equivalent. They have therefore amended the recommendation to allow use of CECT or PET-CT for initial imaging, rather than making FDG PET-CT the preferred option. To aid the decision on when to use FDG PET-CT or CECT, they added additional factors, including availability and patient preference, to the recommendation on factors to take account of when deciding which scanning modality to use for diagnosis. For monitoring response to treatment, they decided to change the recommendation to a

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					weaker 'consider' recommendation for using the same scanning modality used for diagnosis to better reflect some of the uncertainties in the economic model.
British Society of Breast Radiology	Guideline	General	General	For staging CECT the field of view should include from the supraclavicular fossa to the proximal femurs	Thank you for your comment. The committee agreed with your suggestion to specify the field of view of CECT for staging. Therefore, the committee added some text to the recommendation to specify that CECT should cover the chest, abdomen and pelvis (CAP) from the supraclavicular fossa to the proximal femurs.
British Society of Breast Radiology	Guideline	General	General	MRI is mentioned twice in the guideline and we would recommend further reference to this modality as it has utility in bone only disease, pregnant patients and problem solving	Thank you for your comment. While the role of FDG PET-CT for diagnosing and monitoring advanced breast cancer, particularly compared with contrast-enhanced CT, was identified as a priority during scoping, MRI was not. The use of MRI is therefore outside of the scope of this update. However, if you have evidence to support inclusion of this area in future work, please can you share it with us by submitting a topic suggestion through our topic prioritisation process.

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					See here for information on the prioritisation process and the submission form: • Prioritising our guidance topics • Topic suggestion.
Make 2nds Count	Guideline	003	005	Rec 1.1.3 We are concerned that without explicitly stating that discussions about research should take place frequently, throughout a person's treatment pathway, that research options may be only discussed after standard treatment lines are exhausted. A recent UK study suggests prevalent myths in the patient and healthcare professional communities surrounding clinical trials: https://www.thebreastonline.com/article/S0960-9776(25)00861-6/fulltext	Thank you for your comment. The committee noted that suitable clinical trials may not be available at every stage of a person's care for metastatic breast cancer. However, they agreed that it is very important that opportunities are identified and thought about regularly throughout the treatment pathway, and that it is not just after standard treatment lines are exhausted that these discussions are relevant. They therefore amended the existing recommendation about discussing clinical trials to clarify that these discussions should happen throughout the treatment pathway. They also included a cross reference to this recommendation at the start of the section on systemic anticancer therapy.
Make 2nds Count	Guideline	006	003	Rec 1.3.1 The recommendation seems to imply trial availability is a secondary factor in SACT choice. We suggest trial eligibility be assessed as a primary step.	Thank you for your comment. Unless otherwise specified, lists of bullets in NICE recommendations are in no particular order of importance. The committee agreed that all the factors listed were important and so have not

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					changed the order of points in this recommendation.
Make 2nds Count	Guideline	016	013	This rationale states that the committee opted to retain the recommendation despite the underpinning guidance being retired. We would also like to add that the recently published National Cancer Plan specifically mandates access to a specialist nurse for all patients to ensure safety and continuity.	Thank you for your comment. A recommendation about clinical nurse specialists is already present in NICE's guideline on early and locally advanced breast cancer: diagnosis and management. It has been agreed that this recommendation would also apply to people with advanced breast cancer and should also be part of the current guideline. Therefore, a new recommendation has been added to reflect this.
Make 2nds Count	Guideline	General	000	Whilst we welcome the 2026 updates, particularly the shift towards personalised treatment choices, we are concerned that these clinical improvements will not be equitably realised without a mandate for robust data collection. The 2026 guidelines identify a "lack of evidence" for monitoring disease status. This gap can only be filled if recurrence is accurately recorded at the trust level. Despite existing mandates (COSD v10.0), the National Audit of Metastatic Breast Cancer (NaOMe) continues to highlight significant variation, with several trusts reporting zero cases of recurrence in recent 12 month periods. The guideline should explicitly state that the diagnostic and monitoring pathways (Section 1.2) must be integrated with	Thank you for your comment. The committee agreed that accurate data collection and recording is important to support audit, research and quality improvement. They recognised the need for data to be collected to support national efforts, and the fact that this is already mandatory. Due to the variation in adherence, they agreed to make an overarching recommendation in this area.

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				the NAoMe Quality Improvement Intervention launched in October 2025. This ensures that every patient counts and that the data required to resolve current uncertainty in monitoring evidence is captured.	
METUP UK	Guideline	3	25, 1-3	Recommendation 1.2.2 Whilst we acknowledge the guidelines take in to account that FDG PET-CT has higher sensitivity, we would like to see the guidelines making specific reference to the response evaluation criteria of the Response Evaluation Criteria in Solid Tumours (RECIST) and the Positron Emission Tomography Response Criteria in Solid Tumours (PERCIST). Research published in 2022 by Hildbrandt et al highlights the evidence of survival benefit using FDG-PET-CT compared with standard CT imaging; survival benefit is achieved through earlier detection of disease progression. In addition, their research shows when the response evaluation criteria of RECIST and PERCIST are applied using FDG-PET-CT imaging rather than conventional CT imaging, a higher predictive value is shown. We would like to see this evidence reflected in the draft recommendations. Earlier detection of disease progression leads to earlier	Thank you for your comment. The committee were aware of the RECIST and PERCIST criteria used to evaluate treatment response in people with advanced breast cancer. However, they agreed that these are most often used in research settings. Although studies in evidence review B2 (monitoring response to treatment), if any had been identified, might have used RECIST and PERCIST to interpret contrast-enhanced CT and FDG PET-CT imaging, these criteria were not specifically being evaluated. Instead, it was the use of either contrast-enhanced CT or FDG PET-CT and whatever management pathway those imaging results led to which was of interest. No studies were identified for evidence review B2. For these reasons, the committee agreed not to make recommendations about RECIST and PERCIST criteria for evaluating treatment response.

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				access to a new treatment line, potentially providing better effectiveness of that treatment line with less toxicity from being over exposed to a treatment line that has stopped being effective. FDG-PET-CT detects disease progression or regression more sensitively than with standard CT imaging. Hildbrant, M.G., Naghavi-Behzad, M., Vogsen, M. (2022) 'A role of FDG-PT/CT for response evaluation in metastatic breast cancer' Seminars in Nuclear Medicine, 52 (5), pp. 520-530.	Because the effectiveness protocol was limited to randomised controlled trials only, the studies identified in Hildebrandt et al. (2022) were not eligible for inclusion as they were all non-randomised. Evidence from Hildebrandt et al. (2022) was indirectly considered by the committee as part of the health economics work, as it informed the health outcomes for Naghavi-Bezhad et al. (2023) the only previously published economic evaluation identified in the monitoring review. This showed an increase in life expectancy and reduced costs from the use of FDG PET-CT. This was presented to and considered by the committee. The committee highlighted the non-randomised nature of the study and that factors associated with the choice of imaging modality were also likely to impact on overall survival. The expected increase in survival of over 1 year did not match their clinical expectations. Limited weight was therefore placed on the results from the study when considering the health economic evidence in forming recommendations.

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METUP UK	Guideline	3 4	11-16 1-14	Recommendations 1.2.1, 1.2.2 and 1.2.3 Whilst we welcome the draft recommendations, we remain extremely concerned about inequality of access to FDG-PET-CT. Testimonies from our patient groups represent variation in access across the country with alarming differences in sensitivity in imaging results: **Patient quotes:** "I had a PET scan (FDG PET-CT) at the beginning of stage 4 diagnosis to compare with initial MRI and CT scan. Surprisingly there were different results, so frightening really. My oncologist said that all scans are not 100% reliable, as results are based on the size and type of tumour. As for DEXA cans - completely useless for me. I was having DEXA every 18 months pre stage 4 and it didn't pick up anything." "I had MRI, CT and bone scan prior to the secondary diagnosis. But once, when I was about to start chemotherapy, they wanted a clearer answer as to what was going on so they sent me for a PET scan (FDG PET-CT). That's when I got my secondary diagnosis, I'm now just monitored with CT with contrast." "I had CT scan and DEXA scan when my cancer came	Thank you for your comment and patient quotes. We would like to highlight that the guideline committee included patient members who contributed their experiences and perspectives into drafting the recommendations. The patient members on the guideline committee highlighted that there is variation in access to FDG PET-CT, but also noted the value of better diagnosis and monitoring options where possible. The committee noted the issues of FDG PET-CT availability, accessibility and the potential impact on equity as part of their initial discussions when they drafted the recommendations. To try to address this at that time they recommended CECT if FDG PET-CT is not suitable, is inaccessible or is unavailable. Although the economic analysis suggested that FDG PET-CT is highly likely to be cost effective compared with CECT, the committee considered that uncertainties in the evidence base (particularly for monitoring), along with stakeholder and committee concerns around

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				back in 2018, then had CT with contrast every 3 months, it was only when I had progression 4 and a half years later that the doctor switched me to PET-CT scans, and then again when there were some inconclusive areas on my liver. I also started with the MRIs a year ago so they could monitor it more closely. He told me that the MRIs provide a clearer picture of what's going on in the liver."	availability, system capacity and potential inequities in access justified positioning the modalities as equivalent. They have therefore amended the recommendation to allow use of CECT or PET-CT for initial imaging, rather than making FDG PET-CT the preferred option. To aid the decision on when to use FDG PET-CT or CECT, they added additional factors, including availability and patient preference, to the recommendation on factors to take account of when deciding which scanning modality to use for diagnosis. For monitoring response to treatment, they decided to change the recommendation to a weaker 'consider' recommendation for using the same scanning modality used for diagnosis to better reflect some of the uncertainties in the economic model.
METUP UK	Guideline	15	18-21	Recommendations for Research – 2. Platinums for people with BRCA mutation	Thank you for your comment. See NICE's response to METUPUK's other comment on this research recommendation.
METUPUK	Guideline	15	18-21	Evidence suggests greater response rates to platinum chemotherapy in tumours with germline BRCA1/2 mutations. Stratification by BRCA status in clinical and	Thank you for your comment. The protocol for evidence review A included BRCA status as a subgroup of interest, and for some outcomes

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				cost-effectiveness analyses could help with uncertainty and guide "precision" of application. Patient experts at METUPUK emphasise the importance of biomarker-informed treatment and access to appropriate testing to ensure as best we can, that therapies and their associated toxicities are only used for patients most likely to benefit. Byrski, T., Gronwald, J., Huzarski, T., Dent, R., Marczyk, E., Jasiowka, M., Cybulski, C., Sun, P., Narod, S.A. and Lubinski, J., 2010. Response to neoadjuvant cisplatin in BRCA1-positive breast cancer patients. Breast Cancer Research and Treatment, 115(2), pp.359–363. Tutt, A., Tovey, H., Cheang, M.C.U., Kernaghan, S., Kilburn, L., Gazinska, P., Owen, J., Abraham, J., Barrett, S., Barrett-Lee, P., Brown, J., Chan, S., Dowsett, M., Flanagan, J.M., Fox, L., Grigoriadis, A., Gutin, A., Harper-Wynne, C., Hatton, M., Hoadley, K. et al., 2018. Carboplatin in BRCA1/2-mutated and triple-negative breast cancer: the TNT trial. Nature Medicine, 24, pp.628–637. Turner, N.C., Tutt, A.N.J. and Ashworth, A., 2012. Targeting the DNA repair defect of BRCA tumours. Breast Cancer Research, 14(2), p.110.	there was enough information to conduct subgroup analysis by BRCA status. For triple negative breast cancer (TNBC) Tutt et al. (2018) (as per the citation in your comment) and Zhang et al. (2018) contributed data to the subgroup with germline BRCA1 or BRCA2 pathogenic variants for the outcomes of overall survival (OS), progression-free survival (PFS) and objective treatment response rate (OTRR). There were only two studies (Tutt et al. 2018 and Zhang et al. 2018) reporting data by BRCA 1/2 gene status, with a total of 31 participants with germline BRCA1 or BRCA2 pathogenic variants. The committee did not make separate recommendations for people with advanced breast cancer and germline BRCA1 or BRCA2 pathogenic variants because the evidence for triple negative breast cancer was of very low certainty and there was no evidence for other receptor subtypes. They therefore made a research recommendation to generate further evidence instead. No published economic evidence was identified for this review.

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					Regarding the references you include in your comment: • Byrski et al. 2010: does not meet the inclusion criteria for evidence review A as the study looks at people with stage 1 to 3 breast cancer rather than advanced. • Tutt et al. 2018: was included in evidence review A Turner et al. 2005: does not meet the inclusion criteria for evidence review A as it does not contain any primary data.
METUPUK	Guideline	General	General	METUPUK would like to highlight that we did not find this consultation process user-friendly to complete. To support a fully representative account of the patient experience in future we suggest other, less process-driven methods of consultation and information gathering are employed, especially to reach patients experiencing barriers to participation in healthcare generally.	Thank you for your comment. The consultation process used for this guideline is consistent with the consultation process used for all NICE guidelines produced by the Centre for Guidelines. In order to be able to publish guidance in a timely manner, we do limit consultation periods to a set window. We specifically recruit patient representatives to the committee to provide us with information about the patient experience. We also proactively identify patient charities and offer to register them as stakeholders to gather wider feedback.
METUPUK	Guideline	General	General	**Patient-Reported Outcome Measures and Shared Decision Making**	Thank you for your comment. The committee agrees that shared decision making and

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				Outcomes and experiences that are relevant to patient should be at the forefront of the draft recommendations. These include treatment response, progression-free survival, toxicity, and quality of life. Patient reported experience and principles of shared decision making should be embedded in any guidance, following the recommendations of NICE guideline NG197 (shared decision making). We know that many patients won't have a technical understanding of why different imaging choices are made, and these decisions may not be fully explained to them. This limits the possibility for shared decision-making around diagnostic and monitoring processes and to patients accepting doctors' recommendations without question or discussion. When gathering feedback via METUPUK member networks, patients frequently expressed concerns around the discomfort of MRI machines rather than around repeated exposure to CT radiation for example. It is crucial that Multi-Disciplinary Team (MDT) meetings are standardised across the country so that decisions arrived at and agreed within them are disseminated transparently and clearly to patients. As outlined in the	individual factors are key at many points throughout the treatment and care pathway for advanced breast cancer. Patient-reported outcomes were included in all three reviews, including progression-free survival, cancer-specific survival, adverse events of treatments and quality of life for evidence review A, and cancer-specific survival, quality of life and changes to management or treatment for evidence review B. No evidence was identified for quality of life for review A, or any of the listed outcomes for review B. NICE has several foundational guidelines – referenced and hyperlinked at the start of the Advanced breast cancer: diagnosis and treatment guideline – which cover shared decision making, patient experience in adult NHS services and other important topics which are relevant across health areas. In response to stakeholder comments, the committee included the person's preferences in the recommendation about things to take into

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				new National Cancer Plan, the patient perspective should be embedded in all decision making so that patients are fully involved in their care. Patient empowerment is the 'golden thread' running through the plan, and all NICE guidelines and recommendations should reflect this. The National Cancer Plan highlights the need for a change in cancer care from a paternalistic approach to a move towards a new power dynamic of patient empowerment where patients have much more of a participatory role. https://assets.publishing.service.gov.uk/media/699ec931532c9ad91ebbcc64/national-cancer-plan-for-england-delivering-world-class-cancer-care.pdf https://www.nice.org.uk/guidance/ng197	account when deciding between imaging modalities. They agreed that providing practical and logistical information about the different types of scans should be standard practice. They also agreed that it was the clinician's duty to recommend the most accurate imaging modality based on their experience and knowledge of the individual and their clinical characteristics. However, where 2 imaging modalities could be similarly useful then the person's preferences should be taken into account. The committee noted that there is variation across England and Wales in the setup of multidisciplinary teams (MDTs) and who is referred to them. They agreed that, while not every person with advanced breast cancer would need to be discussed in an MDT forum, many cases would. They agreed that this is good practice, but that an evidence review to assess this was not part of the current update. Therefore, no new recommendation has been made in this area.

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METUPUK	EHIA	2		**Question 1: Would it be challenging to implement any of the draft recommendations?** The recommendations of imaging assessment in 1.2.1 of the guidelines would be challenging to implement due to the following **both availability of FDG PET-CT scanners and turnaround time for results.** Geographical availability of FDG PET-CT scanners must be taken into consideration so that guidance acknowledges inequalities. Data published in 2024 ranked the UK the lowest amongst other countries of similar economic development, for numbers of CT, MRI and PET scanners per million population. Any new guidance for the recommended use of FDG-PET-CT scanners must ensure equity of access across the nation to limit the already existing disparities in patient access. The National Quality Board will hopefully address inequality of access by eliminating the current postcode lottery system that currently exists. We remain concerned, as is pointed out in the Equality and Health Inequalities Assessment (EHIA), that women are disproportionately affected by time and financial	Thank you for your comments. The committee noted the issues of FDG PET-CT availability, accessibility and the potential impact on equity as part of their initial discussions when they drafted the recommendations. The section of the guideline on 'Why the committee made the recommendations' that accompanies the diagnostic and monitoring recommendations, the committee discussion of the evidence section of evidence review B and the Equality and Health Inequalities Assessment (EHIA) document acknowledge the geographical variation in the availability of FDG PET-CT and that it could impact travel and wait time for patients. To try to address this in the consultation version of the recommendations, they recommended CECT if FDG PET-CT is not suitable, is inaccessible or is unavailable. Although the economic analysis suggested that FDG PET-CT is highly likely to be cost effective compared with CECT, the committee considered that uncertainties in the evidence base (particularly for monitoring), along with stakeholder and committee concerns around

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				constraints as part of their caring responsibilities. We would like to see the draft recommendations address the difficulties women experience associated with having to travel long distances to access FDG PET-CT scanners. https://uk-pet-core-lab.org.uk/researchers_scanning_facilities.php https://www.gov.uk/government/publications/life-sciences-sector-data-2024/life-sciences-competitiveness-indicators-2024-summary Currently, the maximum Turn Around Time (TAT) for patients undergoing imaging tests and the referring clinician receiving a verified report is four weeks. Due to workforce and resource limitations that target is not routinely met not across the country. Guidelines must acknowledge the geographical inequalities that currently exist, affecting the speed of access to results and clinical effectiveness of any resulting changes to treatment regimens. https://www.england.nhs.uk/long-read/diagnostic-imaging-reporting-turnaround-times/	availability, system capacity and potential inequities in access justified positioning the modalities as equivalent. They have therefore amended the recommendation to allow use of CECT or PET-CT for initial imaging, rather than making FDG PET-CT the preferred option. The committee agreed that this would partly address the fact that women may be affected by time and financial constraints linked to caring responsibilities. However, difficulties with needing to travel to access imaging, even if CECT is available relatively locally, will remain an issue for some people and are beyond NICE's ability to address. To aid the decision on when to use FDG PET-CT or CECT, they added additional factors, including availability and patient preference, to the recommendation on factors to take account of when deciding which scanning modality to use for diagnosis. For monitoring response to treatment, they decided to change the recommendation to a weaker 'consider' recommendation for using the same scanning modality used for diagnosis to

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					better reflect some of the uncertainties in the economic model.
METUPUK	Evidence review B	5	15-17	**Question 2: Would implementation of any of the draft recommendations have significant cost implications?** The cost implications of the draft recommendations are enormous. The report, 'The impact of NHS workforce shortfalls on cancer patients', published in October 2025, highlights the gaps in the radiography workforce. Significant investment in the clinical oncology workforce is required to ensure that the needs of metastatic breast cancer patients are met. The Royal College of Radiologists state that an increase in workforce numbers has not kept up with demand for services. There was a shortfall in the clinical oncology workforce of around 15% in 2024. This looks set to increase to 19% by 2029. If the draft recommendations in these guidelines are to be met, significant investment in the cancer workforce is needed. The Royal College of Radiologists 2024 Clinical Radiology Workforce Census shows that the UK radiology workforce is facing a severe, worsening shortage with a 29%-31% shortfall of consultants. Demand for CT and MRI scans is outstripping workforce growth causing severe patient	Thank you for your comments. Evidence review B found moderate to very low certainty evidence that FDG PET-CT may have high sensitivity for diagnosing metastatic disease, and low to very low certainty evidence that CECT may have moderate sensitivity. Low certainty evidence suggested both tests may have high specificity. There was no evidence identified for FDG PET-CT for monitoring response to treatment. The recommendation about monitoring was based on the experience of the committee and the health economic model which used the assumption that FDG PET-CT and CECT were likely to perform in a similar way for monitoring as they did for diagnosis. The committee noted the issues of FDG PET-CT availability, accessibility and the potential impact on equity as part of their initial discussions when they drafted the recommendations. To try to address this at that time they recommended CECT if FDG PET-CT is not suitable, is inaccessible

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				diagnosis delays. https://commonslibrary.parliament.uk/research-briefings/cdp-2025-0186/ https://www.rcr.ac.uk/media/4imb5jge/_rcr-2024-clinical-radiology-workforce-census-report.pdf	or is unavailable. Although the economic analysis suggested that FDG PET-CT is highly likely to be cost effective compared with CECT, the committee considered that uncertainties in the evidence base (particularly for monitoring), along with stakeholder and committee concerns around availability, system capacity and potential inequities in access justified positioning the modalities as equivalent. They have therefore amended the recommendation to allow use of CECT or PET-CT for initial imaging, rather than making FDG PET-CT the preferred option. To aid the decision on when to use FDG PET-CT or CECT, they added additional factors, including availability and patient preference, to the recommendation on factors to take account of when deciding which scanning modality to use for diagnosis. For monitoring response to treatment, they decided to change the recommendation to a weaker 'consider' recommendation for using the same scanning modality used for diagnosis to

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					better reflect some of the uncertainties in the economic model.
METUP UK	Evidence Review B	8	16	In unselected advanced triple negative breast cancer, platinum regimens are effective but not consistently superior across all outcomes. We would urge the draft recommendations to consider analysing effectiveness and cost-effectiveness separately for biologically different patient groups, rather than treating all advanced breast cancer as one population, as patient response to platinum chemotherapy can differ significantly. Around 50% of triple negative breast cancer cases have mutations that hold traits of homologous recombination deficiency (HRD). Detailed genomic profiling is essential for the presence of HRD to be identified to inform chemotherapy pathways, so that it is a cost-effective use of resources. It would create the opportunity for personalised patient treatment pathways and help mitigate unnecessary toxicity. In patient groups who test positive for HRD, platinum-containing chemotherapy is potentially a better treatment option because in platinum free treatment, patients experience a shorter period of time without disease progression.1	Thank you for your comment. The protocol for evidence review A did not include specific subgroup analysis of people who are homologous recombination deficiency (HRD). The committee agreed that HRD status is not routinely tested for in the NHS, and there is insufficient published evidence to be able to conduct an analysis for this group. Two of the studies included in evidence review A (Tutt et al. 2018, Zhang et al. 2018) included analyses about HRD. Although these weren't used in the review, the NICE team note that the results were mixed: Tutt et al. (2018) concluded that there was not a better response to platinum compared with docetaxel in patients with HRD, while Zhang et al. (2018) found a statistically significant interaction between HR status and treatment for PFS and objective treatment response, but not for OS. Yimeng et al. (2021) would not be eligible for inclusion in evidence review A because it is not a randomised trial.

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				Yimeng, C., Cui, L., Zhang, B., Zhao, X., Xu, B. (2021) 'Efficacy of platinum-based chemotherapy in advanced triple-negative breast cancer in association with homologous recombination deficiency. Journal of Clinical Oncology, 39 (15) e13051 https://ascopubs.org/doi/10.1200/JCO.2021.39.15_suppl.e13051	Evidence review A did include BRCA gene status as a subgroup of interest. For some outcomes there was enough information to conduct subgroup analysis by BRCA status. For triple negative breast cancer (TNBC) Tutt et al. (2018) and Zhang et al. (2018) contributed data to the subgroup with a germline BRCA1 or BRCA2 pathogenic variants for the outcomes of overall survival (OS), progression-free survival (PFS) and objective treatment response rate (OTRR). The committee did not make separate recommendations for people with advanced breast cancer and germline BRCA1 or BRCA2 pathogenic variants because the evidence for TNBC was of very low certainty and there was no evidence for other receptor subtypes. They therefore made a research recommendation about platinum-based chemotherapy for people with germline BRCA1 or BRCA2 pathogenic variants. Genomics and genetic testing were not part of the scope of this update. As they were not assessed, no specific recommendations about types of tests could be made. However, the

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					committee agreed that the guideline should signpost to the National Genomics Test Directory and so a new recommendation was added to do this. They also included a cross reference to the NICE guideline on Familial Breast cancer (CG164) that is currently being updated.
METUP UK	Evidence Review B	41	8-11	The patient quotes in METUPUK's response are from people who are treated at teaching hospitals with strong links to hospitals in London and Cambridge. A question about whether patients had experience with FDG PET-CT scans might have elicited different answers in different geographical areas.	Thank you for your comment. Please see NICE's responses to METUPUK's other comments regarding FDG PET-CT. The committee agreed that in their experience access to this type of imaging is variable and geographically dependent.
NHS England	Guideline	002	003	The guideline should recommend that all newly diagnosed or complex metastatic patients are discussed and recorded at MDT. Implementing this would: • Enable the capture of stage 4 prevalence data, which would support national service planning. • Address a clinical governance gap. MDT discussion is standard for earlier stage disease and it is not clear why this is not recommended for this cohort • Provide the activity baseline needed to assess the resource implications of other recommendations in this	Thank you for your comment. The committee noted that there is variation across England and Wales in the setup of multidisciplinary teams (MDTs) and who is referred to them. They agreed that, while not every person with advanced breast cancer would need to be discussed in an MDT forum, many cases would. They agreed that this is good practice, but that an evidence review to assess this was not part of the current update. Therefore, no new recommendation has been made in this area.

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				guideline, including the proposed shift to FDG PET-CT as first-line imaging	
NHS England	Guideline	005	007	This recommendation (using the same modality to monitor response to treatment) risks compounding potential pressures on PET-CT capacity, which NICE has not considered as part of its evidence review. It will be necessary for NICE to factor this into any capacity and activity modelling.	Thank you for your comment. In drafting recommendations, we have considered the clinical and cost -effectiveness evidence and asked the committee about implementation challenges. NICE develops resource impact tools which we publish alongside clinical guidelines on the website. The resource impact tools will reflect the additional capacity pressure on PET-CT capacity. Evidence review B found moderate to very low certainty evidence that FDG PET-CT may have high sensitivity for diagnosing metastatic disease, and low to very low certainty evidence that CECT may have moderate sensitivity. Low certainty evidence suggested both tests may have high specificity. There was no evidence identified for FDG PET-CT for monitoring response to treatment. The recommendation about monitoring was based on the experience of the committee and the health economic

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					model which used the assumption that FDG PET-CT and CECT were likely to perform in a similar way for monitoring as they did for diagnosis. The committee noted the issues of FDG PET-CT availability, accessibility and the potential impact on equity as part of their initial discussions when they drafted the recommendations. To try to address this at that time they recommended CECT if FDG PET-CT is not suitable, is inaccessible or is unavailable. Although the economic analysis suggested that FDG PET-CT is highly likely to be cost effective compared with CECT, the committee considered that uncertainties in the evidence base (particularly for monitoring), along with stakeholder and committee concerns around availability, system capacity and potential inequities in access justified positioning the modalities as equivalent. They have therefore amended the recommendation to allow use of CECT or PET-CT for initial imaging, rather than

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					making FDG PET-CT the preferred option. To aid the decision on when to use FDG PET-CT or CECT, they added additional factors, including availability and patient preference, to the recommendation on factors to take account of when deciding which scanning modality to use for diagnosis. For monitoring response to treatment, they decided to change the recommendation to a weaker 'consider' recommendation for using the same scanning modality used for diagnosis to better reflect some of the uncertainties in the economic model.
NHS England	Guideline	General	000	Very comprehensive, and for the imaging and assessment pathways the flow of the text document works well. See above for importance and userability of the visual summary	Thank you for your comment and support for this guideline update.
NHS England	Guideline / Evidence Review [B]	003	011	Further analysis is needed before NICE can recommend FDG PET-CT as first line assessment. This includes expanding the evidence review to: a) model system-level activity to estimate potential volume of PET-CT scans because of this recommendation; and b) produce a budget impact analysis of any increased volume.	Thank you for your comments. Evidence review B found moderate to very low certainty evidence that FDG PET-CT may have high sensitivity for diagnosing metastatic disease, and low to very low certainty evidence that CECT may have moderate sensitivity. Low certainty evidence suggested both tests may have high specificity.

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				It is likely that the population eligible for PET-CT will be significant, as it will cover not just patients with confirmed metastases, but everyone being scanned to rule it out. This will have significant impact on existing capacity and could create bottlenecks that could extend waiting times for cancer patients. Moreover, this would also likely result in changes in commissioning policy before implementation, as the recommendation as worded falls outside current commissioned indications for FDG PET-CT in breast cancer. The closest commissioned use is "assessment of extent of disease in selected patients with disseminated breast cancer before therapy" which covers confirmed disease in selected patients, not first-line staging for all suspected metastatic disease. This recommendation also contradicts British Society of Breast Radiology (BSBR) guidance, which reserves PET-CT for specific indications in breast cancer (e.g. inflammatory breast cancer, problem solving and in patients with oligometastatic disease where radical therapies depend on excluding metastases).	There was no evidence identified for FDG PET-CT for monitoring response to treatment. The recommendation about monitoring was based on the experience of the committee and the health economic model which used the assumption that FDG PET-CT and CECT were likely to perform in a similar way for monitoring as they did for diagnosis. NICE develops resource impact tools which publish alongside clinical guidelines on the website. The resource impact tools will reflect the additional capacity pressure on PET-CT capacity. The committee noted the issues of FDG PET-CT availability, accessibility and the potential impact on equity as part of their initial discussions when they drafted the recommendations. To try to address this at that time they recommended CECT if FDG PET-CT is not suitable, is inaccessible or is unavailable.

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					The committee agreed that their draft recommendations did not correspond to the BSBR guidance and may impact the commissioning policy, but they were written based on the committee's experience and interpretation of the evidence they reviewed. Although the economic analysis suggested that FDG PET-CT is highly likely to be cost effective compared with CECT, the committee considered that uncertainties in the evidence base (particularly for monitoring), along with stakeholder and committee concerns around availability, system capacity and potential inequities in access justified positioning the modalities as equivalent. They have therefore amended the recommendation to allow use of CECT or PET-CT for initial imaging, rather than making FDG PET-CT the preferred option. To aid the decision on when to use FDG PET-CT or CECT, they added additional factors, including availability and patient preference, to the recommendation on factors to take account of when deciding which scanning modality to use for diagnosis.

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					For monitoring response to treatment, they decided to change the recommendation to a weaker 'consider' recommendation for using the same scanning modality used for diagnosis to better reflect some of the uncertainties in the economic model.
NHS England	Visual summary	General	000	This is excellent and a really user-friendly way for clinicians to navigate the increasingly complex treatment pathways. The clickable links to the relevant TAs very useful	Thank you for your comment and support for the visual summary.
Royal College of General Practitioners	Guideline	002	001	We agree that the continuation of the "key worker" role is vital. It provides a clear and consistent point of contact, supporting coordination of complex care needs across multiple services and facilitating effective communication with primary care.	Thank you for your comment. A recommendation about clinical nurse specialists is already present in NICE's guideline on early and locally advanced breast cancer: diagnosis and management. It has been agreed that this recommendation would also apply to people with advanced breast cancer and should also be part of the current guideline. Therefore, a new recommendation has been added to reflect this.
Royal college of General Practitioners	Guideline	General	General	We support the recommendation to discuss opportunities for people with advanced breast cancer to be involved in research, including clear communication of the potential benefits and risks of participation in clinical trials and other studies. Supporting individuals to take part, where they	Thank you for your comment. Involvement of family members and/or carers is addressed in the NICE guideline on Patient experience in adult NHS services (recommendation 1.3.10). We cross refer to this recommendation from a

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				wish to do so, is an important component of person-centred care. We suggest that this could be broadened to explicitly include carers, where appropriate. Unpaid carers play a significant role in supporting people with advanced illness and bring valuable perspectives that can inform research design, delivery, and outcomes. Involving carers can help ensure that research better reflects real-world experiences and priorities, and can improve the relevance and applicability of findings. Including carers alongside patients in discussions about research opportunities would therefore support a more holistic and inclusive approach.	box that will sit at the start of each section of recommendations. The committee also agreed that the recommendation on discussing opportunities for people to be involved in research should remain focussed on the individual with metastatic breast cancer to emphasise the importance of this recommendation for that group specifically. Therefore, the recommendation has not been amended to include carers.
Royal College of General Practitioners	Guideline	General	000	We agree that explicitly referencing the guideline on depression in people with chronic physical health problems is helpful. It supports GPs in recognising and managing the significant psychological burden associated with advanced cancer, and promotes a more holistic approach to care.	Thank you for your comment, and your support for this recommendation.
Royal College of General Practitioners	Guideline	General	000	Overall, we consider that the guideline is well developed. It provides clear pathways and uses appropriate, consistent terminology, which supports understanding and implementation in clinical practice.	Thank you for your comment, and your support for this guideline update.

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Royal College of Nursing	Guideline	General	000	We don't have any feedback at this stage.	Thank you for this comment.
The British Nuclear Medicine Society	Guideline	General	000	The BNMS are supportive of these guidelines and welcome the updates.	Thank you for your comment and support for this guideline update.
The Institute of Cancer Research, London	Guideline	021	028	We believe that there is a suitable challenge to the notion that there was "very little evidence for the effectiveness of platinum-based chemotherapy for people with advanced breast cancer who have a germline BRCA mutation, and this was limited to people who also had TNBC", as discussed in the page and line numbers referenced. The TNT trial (Carboplatin in BRCA1/2-mutated and triple-negative breast cancer BRCAness subgroups: the TNT Trial | Nature Medicine), which compared carboplatin monotherapy to docetaxel monotherapy, showed similar efficacy in unselected TNBC, but carboplatin was significantly more effective (double the objective response rate – 68 per cent versus 33 per cent) in patients with germline BRCA1/2 mutations. Furthermore, the CBCSG006 trial – as reported in The Lancet Oncology – demonstrated that cisplatin plus gemcitabine was superior to paclitaxel plus gemcitabine	Thank you for this comment. We confirm that the TNT trial (Tutt et al. 2018) and the CBCSG006 trial (Hu et al. 2015) were both included in the Cochrane review by Egger et al. (2020) which was included in evidence review A (see evidence review A for full citations and links to all studies). Hu et al (2015) was reported as Zhang et al. (2018) in both the Egger et al. (2020) review and in evidence review A, as the more recent publication. Both studies reported on people with triple negative breast cancer (TNBC) only. Tutt et al. (2018) and Zhang et al. (2018) both contributed data to the analyses on overall survival (OS) (Figures 1 to 4), progression free survival (PFS) (Figures 5 to 8), objective tumour response rate (OTRR) (Figures 9 to 13) as well as adverse events. Data was extracted for the

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				for first-line treatment of metastatic TNBC, with improved progression free survival (7.73 vs 6.47 months) and higher objective response rates (53.0 per cent versus 32.1 per cent).	subgroup with germline BRCA1 or BRCA2 pathogenic variants as follows: • Tutt et al (2018): OS, PFS, OTRR • Zhang et al. (2018): PFS, OTRR As there were only two studies (Tutt et al. 2018 and Zhang et al. 2018) reporting data by BRCA 1/2 gene status, with a total of 31 participants with BRC germline BRCA1 or BRCA2 pathogenic variants, we think the statement that very little evidence was identified about the effectiveness of platinum-based chemotherapy for people with advanced breast cancer who have germline BRCA1 or BRCA2 pathogenic variants is justified. However, as the key issue is that the evidence was of very low certainty, we have amended the wording to reflect this. Both studies included only people with TNBC meaning no evidence for other receptor subtype was identified.
The Pan Alliances Breast Cancer Group	Guideline	General	000	**PET-CT positioning and evidence** • Concern that routine PET-CT for diagnosis and monitoring is being recommended without clear supporting evidence of superiority over CT.	Thank you for your comments. Evidence review B found moderate to very low certainty evidence that FDG PET-CT may have high sensitivity for diagnosing metastatic disease, and low to very low certainty evidence that CECT may have

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				• The recommendation appears to go beyond current international guidance (e.g. ESMO/NCCN) and is discordant with BSBR guidance. • Significant national capacity constraints exist (scanner availability, radioisotope supply, radiologist reporting capacity). • Risk that recommending PET-CT as standard could increase regional inequity in access. • PET-CT type is not specified. Not all PET-CT scans include a full diagnostic CT and in such cases may be inferior for detecting some metastatic sites (e.g. liver). • Suggest PET-CT be presented as an option in selected situations rather than routine imaging. The draft appears to position FDG PET-CT as the preferred modality for diagnosis and staging, with CECT suggested where PET-CT is not suitable or accessible. It also recommends using the same primary imaging modality for monitoring response. However, the rationale acknowledges that there is limited direct comparative evidence in this setting, and that the monitoring recommendation is largely based on committee experience rather than direct evidence. Could PET-CT be	moderate sensitivity. Low certainty evidence suggested both tests may have high specificity. There was no evidence identified for FDG PET-CT for monitoring response to treatment. The recommendation about monitoring was based on the experience of the committee and the health economic model which used the assumption that FDG PET-CT and CECT were likely to perform in a similar way for monitoring as they did for diagnosis. The committee noted the issues of FDG PET-CT availability, accessibility and the potential impact on equity as part of their initial discussions when they drafted the recommendations. To try to address this at that time they recommended CECT if FDG PET-CT is not suitable, is inaccessible or is unavailable. The committee agreed that their draft recommendations did not correspond to the BSBR guidance, but they were written based on the committee's experience and interpretation of the evidence they reviewed.

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				framed more clearly as an option in selected situations rather than the implied default?	Although the economic analysis suggested that FDG PET-CT is highly likely to be cost effective compared with CECT, the committee considered that uncertainties in the evidence base (particularly for monitoring), along with stakeholder and committee concerns around availability, system capacity and potential inequities in access justified positioning the modalities as equivalent. They have therefore amended the recommendation to allow use of CECT or PET-CT for initial imaging, rather than making FDG PET-CT the preferred option. To aid the decision on when to use FDG PET-CT or CECT, they added additional factors, including availability and patient preference, to the recommendation on factors to take account of when deciding which scanning modality to use for diagnosis. For monitoring response to treatment, they decided to change the recommendation to a weaker 'consider' recommendation for using the same scanning modality used for diagnosis to

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					better reflect some of the uncertainties in the economic model. The committee discussed whether to provide more information about the PET-CT type. The recommendations in this guideline specifically refer to the use of fluorodeoxyglucose (FDG) PET-CT, where FDG is the tracer. The committee discussed this and agreed that the CT element in FDG PET-CT scan is usually non-contrast and so will not produce vascular imaging, but the PET element of the CT helps to bridge this gap. Therefore, they agreed not to make any changes to how FDG PET-CT is referred to in the guideline.
The Pan Alliances Breast Cancer Group	Guideline	General	000	**Deliverability and equity** The guideline itself recognises that PET-CT access and reporting capacity vary across the NHS. Recommending PET-CT as the preferred modality for both diagnosis and monitoring risks creating a pathway that cannot currently be delivered equitably across regions, which could inadvertently increase variation in care.	Thank you for your comment. The committee noted the issues of FDG PET-CT availability, accessibility and the potential impact on equity as part of their initial discussions when they drafted the recommendations. To try to address this at that time they recommended CECT if FDG PET-CT is not suitable, is inaccessible or is unavailable.

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					Although the economic analysis suggested that FDG PET-CT is highly likely to be cost effective compared with CECT, the committee considered that uncertainties in the evidence base (particularly for monitoring), along with stakeholder and committee concerns around availability, system capacity and potential inequities in access justified positioning the modalities as equivalent. They have therefore amended the recommendation to allow use of CECT or PET-CT for initial imaging, rather than making FDG PET-CT the preferred option. To aid the decision on when to use FDG PET-CT or CECT, they added additional factors, including availability and patient preference, to the recommendation on factors to take account of when deciding which scanning modality to use for diagnosis. For monitoring response to treatment, they decided to change the recommendation to a weaker 'consider' recommendation for using the same scanning modality used for diagnosis to better reflect some of the uncertainties in the economic model.

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The Pan Alliances Breast Cancer Group	Guideline	General	000	**Lobular breast cancer** The draft also notes the limitations of FDG PET-CT in invasive lobular carcinoma, where uptake may be lower and diagnostic accuracy less certain. Given this subtype forms 10% of all diagnosed breast cancers and how frequently this subtype raises diagnostic uncertainty in practice, it would be helpful to highlight this subgroup when considering the overall imaging strategy.	Thank you for your comment. Evidence review B specified people with lobular breast cancer as a population group of interest. However, only one study was identified which provided evidence on the diagnostic test accuracy of FDG PET-CT for people with lobular breast cancer specifically, and no evidence for CECT in the same group was found. The evidence suggested FDG PET-CT may have low sensitivity for lobular breast cancer (compared with high sensitivity in the overall population). The committee included a bullet point under the factors to take into account when choosing an imaging modality to refer to breast cancers that may show lower levels of FDG uptake and this includes lobular breast cancer as an example. They were unable to make a recommendation about the best types of imaging modality for the diagnosis and monitoring of lobular breast cancer because this was not the object of the current review and they had not looked at the evidence for imaging modalities other than FDG PET-CT and CECT. However, the committee identified this area as a gap and made a research recommendation to

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					attempt to identify diagnostically accurate imaging modalities for people with lobular breast cancer. This suggests research comparing whole body MRI and other newer tracers to be used with PET-CT in place of FDG. This issue is highlighted in the committee discussion section of the evidence review B. Therefore, as the committee were unable to recommend other types of imaging for lobular breast cancer, no changes were made to the recommendations around this.
The Pan Alliances Breast Cancer Group	Guideline	General	000	**Imaging pathway clarity** While the draft gives relatively clear guidance on imaging modality, it is less clear on the broader clinical pathway, particularly who should undergo staging imaging and the role and frequency of imaging when monitoring advanced disease. A little more clarity here may help reduce variation in interpretation and practice.	Thank you for your comment. We have not looked at any evidence relating to criteria for staging or the role and frequency of imaging because they were out of scope of this guideline update. The committee also noted that, in practice, the monitoring schedule for people with advanced breast cancer is tailored to the individual and therefore it would be difficult to provide guidance on this matter. They also noted that there is BSBR guidance on indications for whole-body staging in breast cancer (section 5) that is in need of updating and that the question of who to image might be

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					better covered by professional societies such as the BSBR. Therefore, the committee were unable to provide information about the topics you raised, and no changes were made to the recommendations.
The Pan Alliances Breast Cancer Group	Guideline	General	000	**Brain imaging** Guidance focuses on MRI brain in symptomatic patients but does not address whether or not brain imaging should be considered in asymptomactic patients.	Thank you for your comment. Brain imaging is outside of the scope of this update and guideline. This is likely to come under the scope of the NICE guideline on brain tumours (primary) and brain metastases in over 16s (NG99) rather than the current work on advanced breast cancer. If this is not covered in NG99 and you have evidence to support inclusion of brain imaging in people with brain tumours who are asymptomatic 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 Pan Alliances Breast Cancer Group	Guideline	General	000	**Local therapy in oligometastatic disease** The management sections otherwise focus largely on traditional palliative approaches, and the evolving role of local ablative strategies in carefully selected patients with oligometastatic or oligoprogressive disease is not clearly reflected. In contemporary multidisciplinary practice this may include approaches such as stereotactic ablative radiotherapy (SABR), metastasectomy, or image-guided ablative techniques (e.g. radiofrequency or cryoablation) in appropriate settings. While the evidence base continues to evolve and careful patient selection remains essential, some of these approaches are already commissioned or used within specialist services as exemplified by the lack of reference to the 'Clinical Commissioning Policy Stereotactic ablative radiotherapy (SABR) for patients with metachronous extracranial oligometastatic cancer (all ages) (URN:1908) [200205P]'Acknowledging this developing treatment paradigm may help ensure the guidance reflects current multidisciplinary practice and that the best standards of care are delivered.	Thank you for your comments. Local therapy for oligometastatic disease is outside of the scope of this update. However, if you have evidence to support inclusion of this area 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.
The Pan Alliances	Guideline	General	000	**Pathology.**	Thank you for your comment. The recommendation on pathological assessment was not within the scope of this update and was

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Breast Cancer Group				Concern that the following statement below should be a standard of care rather than a consideration: *Pathological assessment 2 1.2.6 For people whose breast cancer has progressed, **consider** reassessing 3 their hormone receptor (HR) and human epidermal growth factor receptor 4 2 (HER2) status if a change in receptor status will lead to a change in 5 management. [2017, amended 2026]*	greyed out at consultation to reflect this. We note that the word 'consider' is used in NICE recommendations to indicate a weak – rather than a strong – recommendation. This is based on an assessment of the strength of the evidence and the balance of benefits and harms at the time the recommendation was made. 'Consider' is not intended to mean 'think about' in NICE recommendations. For more information see developing NICE guidelines: the manual.
The Pan Alliances Breast Cancer Group	Guideline	General	000	**MDT discussion** No explicit reference is made to multidisciplinary team discussion of patients with advanced breast cancer. There should be a reference to such MDT discussions and their role in the care of patients with advanced breast cancer, this is particularly important given the rapidity of advances and the increasingly complex nature of managing these patients. Therefore, having available a forum to discussion such cases is vital.	Thank you for your comment. The committee noted that there is variation across England and Wales in the setup of multidisciplinary teams (MDTs) and who is referred to them. They agreed that, while not every person with advanced breast cancer would need to be discussed in an MDT forum, many cases would. They agreed that this is good practice, but that an evidence review to assess this was not part of the current update. Therefore, no new recommendation has been made in this area.

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The Pan Alliances Breast Cancer Group	Guideline	General	000	**Collecting data on people with advanced breast cancer** No mention is made of collecting data on newly diagnosed patients with advanced breast cancer. Such data collection is mandatory. The guidance offers an opportunity to reinforce the importance of ensuring this data is collected. Such data collection is key to service planning, benchmarking, research and planning staffing needs. In addition, this is a clear ask by people living with the disease patients want to see, therefore the lack of any mention of mandated data collection will be seen negatively by women and men living with secondary breast cancer.	Thank you for your comment. The committee agreed that accurate data collection and recording is important to support audit, research and quality improvement. They recognised the need for data to be collected to support national efforts, and the fact that this is already mandatory. Due to the variation in adherence, they agreed to make an overarching recommendation in this area.
The Pan Alliances Breast Cancer Group	Guideline	General	000	**Clinical Nurse Specialist Support** The guideline appropriately refers to assessing supportive care needs and continuity through a "key worker." The recently published The National Cancer Plans mandate that all patients have a CNS, therefore the guidance should explicitly state that every patient with advanced breast cancer should have access to a clinical nurse specialist to support and coordinated care.	Thank you for your comment. A recommendation about clinical nurse specialists is already present in NICE's guideline on early and locally advanced breast cancer: diagnosis and management. It has been agreed that this recommendation would also apply to people with advanced breast cancer and should also be part of the current guideline. Therefore, a new recommendation has been added to reflect this.

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The Pan Alliances Breast Cancer Group	Guideline	General	000	**Palliative Care and Enhanced Supportive Care** The guideline refers to palliative care in the context of uncontrolled local disease are assessed. :The guidance however not does mention or refer to importance of Enhanced Supportive Care (ESC) in the care of patients with treatable but not curable cancers such as advanced breast cancer and the importance of early referral, and the provision of holistic care. There is clear national policy on ESC and no reference is made to this. It is not clear if the input of nay subject matter experts were involved in the development of these guidelines from the perspective of ESC.	Thank you for your comment. Palliative care is outside of the scope of this update and the advanced breast cancer guideline because it is covered in detail in other NICE guidance on end of life care for adults and care of dying adults in the last days of life. Cross references to these guidelines are included in the section on Managing uncontrolled local disease and metastases. However, we note that neither of these guidelines currently cover Enhanced Supportive Care. Any suggestions for updates to topics related to palliative care need to be made via the topic suggestion links below in relation to these guidelines. See here for information on the prioritisation process and the submission form: • Prioritising our guidance topics • Topic suggestion.
The Pan Alliances Breast Cancer Group	Guideline	General	000	**Genomics:** No mention of genomics both germ line or somatic testing is made. It would be useful to mention these with relevant signposting to test directory regarding criteria and tissue testing vs ctDNA. This is particularly important given patients who develop metastatic breast cancer may not	Thank you for your comment. Genomics and genetic testing were not part of the scope of this update. As they were not assessed, no specific recommendations about types of tests could be made. However, the committee agreed that the guideline should signpost to the National

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				have been eligible for germline genetic testing at the time of their initial diagnosis but are at relapse eg women and men with ERpos, HER2 negative MBC or it did not exist at the time of their initial diagnosis.	Genomics Test Directory and so a new recommendation was added to do this. They also included a cross reference to the NICE guideline on Familial Breast cancer (CG164) that is currently being updated.
The Pan Alliances Breast Cancer Group	Guideline	General	000	**Best Practice:** Given the readily evolving nature of treating advanced breast cancer the referencing ESMO living guidelines as a source of information for up to date information would be useful https://www.esmo.org/guidelines/living-guidelines/esmo-living-guideline-metastatic-breast-cancer	Thank you for your comment. The committee were aware of other existing guidance covering the diagnosis and management of advanced breast cancer, including the ESMO guidelines. However, original reviews were undertaken for the review questions in the scope and therefore these guidelines were not formally assessed as part of this update. Therefore, they would not be linked to as part of NICE's standard methods.
UK Breast Cancer Group	Guideline	General	000	**MDT discussion** No explicit reference to patients with metastatic breast cancer being discussed in a multidisciplinary team, which is standard practice and part of many previous guidance documents (eg Secondary Not Second rate, Breast Cancer Now 2017.) This is also part of the National Audit of Metastatic Breast Cancer (NAoMe, 2025) and should therefore clearly be defined in this updated NICE guidance.	Thank you for your comment. The committee noted that there is variation across England and Wales in the setup of multidisciplinary teams (MDTs) and who is referred to them. They agreed that, while not every person with advanced breast cancer would need to be discussed in an MDT forum, many cases would. They agreed that this is good practice, but that an evidence review to assess this was not part of the current update. Therefore, no new recommendation has been made in this area.

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UK Breast Cancer Group	Guideline	General	000	**Supportive care** The guideline refers to a "key worker" as part of supportive care but previous reports and guidelines have made key reference to specialist advanced breast cancer CNS support and The National Cancer Plans mandates that all patients have a CNS (Secondary Not Second rate, Breast Cancer Now 2017; NAoMe, 2025.)	Thank you for your comment. A recommendation about clinical nurse specialists is already present in NICE's guideline on early and locally advanced breast cancer: diagnosis and management. It has been agreed that this recommendation would also apply to people with advanced breast cancer and should also be part of the current guideline. Therefore, a new recommendation has been added to reflect this.
UK Breast Cancer Group	Guideline	General	000	**Imaging in initial diagnosis and follow up in ABC** • Concern that routine imaging suggested conflicts with British Society of Breast Radiology (BSBR)and international guidance (e.g. ESMO/NCCN). • The BSBR, the expert group in this area, have produced updated guidance (October 2025) for both initial and follow up scanning. • This conflict is particularly around the use of PET-CT and we would thus suggest the BSBR guidance should be utilised. • PET-CT type is not specified. Not all PET-CT scans include a full diagnostic CT and, in such cases, may be inferior for detecting some metastatic sites (e.g. liver). Suggest PET-CT be presented as an option in selected situations rather than routine imaging.	Thank you for your comments. The committee agreed that their draft recommendations did not correspond to the BSBR guidance, but they were written based on the committee's experience and interpretation of the evidence they reviewed. Evidence review B found moderate to very low certainty evidence that FDG PET-CT may have high sensitivity for diagnosing metastatic disease, and low to very low certainty evidence that CECT may have moderate sensitivity. Low certainty evidence suggested both tests may have high specificity. There was no evidence identified for FDG PET-CT for monitoring response to treatment. The recommendation

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					about monitoring was based on the experience of the committee and the health economic model which used the assumption that FDG PET-CT and CECT were likely to perform in a similar way for monitoring as they did for diagnosis. The committee noted the issues of FDG PET-CT availability, accessibility and the potential impact on equity as part of their initial discussions when they drafted the recommendations. To try to address this at that time they recommended CECT if FDG PET-CT is not suitable, is inaccessible or is unavailable. Although the economic analysis suggested that FDG PET-CT is highly likely to be cost effective compared with CECT, the committee considered that uncertainties in the evidence base (particularly for monitoring), along with stakeholder and committee concerns around availability, system capacity and potential inequities in access justified positioning the modalities as equivalent. They have therefore

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					amended the recommendation to allow use of CECT or PET-CT for initial imaging, rather than making FDG PET-CT the preferred option. To aid the decision on when to use FDG PET-CT or CECT, they added additional factors, including availability and patient preference, to the recommendation on factors to take account of when deciding which scanning modality to use for diagnosis. For monitoring response to treatment, they decided to change the recommendation to a weaker 'consider' recommendation for using the same scanning modality used for diagnosis to better reflect some of the uncertainties in the economic model. The committee discussed whether to provide more information about the PET-CT type. The recommendations in this guideline specifically refer to the use of fluorodeoxyglucose (FDG) PET-CT, where FDG is the tracer. The committee agreed that the CT element in FDG PET-CT scan is usually non-contrast and so will not produce vascular imaging, but the PET

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					element of the CT helps to bridge this gap. Therefore, they agreed not to make any changes to how FDG PET-CT is referred to in the guideline.
UK Breast Cancer Group	Guideline	General	000	**Local therapy in oligometastatic disease** • New techniques for oligometastatic or oligoprogressive disease is not clearly reflected. The use of specialised local MDMs to select suitable patients for locally commissioned treatments such as stereotactic ablative radiotherapy (SABR), metastasectomy, or image-guided ablative techniques (e.g. radiofrequency or cryoablation) is not adequately indicated.	Thank you for your comment. Local therapy for oligometastatic disease is outside of the scope of this update. However, if you have evidence to support inclusion of this area 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. The committee noted that there is variation across England and Wales in the setup of multidisciplinary teams (MDTs) and who is referred to them. They agreed that, while not every person with advanced breast cancer would need to be discussed in an MDT forum, many cases would. They agreed that this is good practice, but that an evidence review to

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					assess this was not part of the current update. Therefore, no new recommendation has been made in this area.
UK Breast Cancer Group	Guideline	General	000	**National data capture** The NAoMe 2025 report identifies the failure of current data to accurately capture the incidence and prevalence of recurrent and metastatic disease. This is affecting appropriate resourcing of ABC within the UK and some reference to ensuring correct capture of data within MDMs and thus improves returns to national datasets (e.g. COSD); should be part of the responsibility of all within the MDMs and thus included in this guidance.	Thank you for your comment. The committee agreed that accurate data collection and recording is important to support audit, research and quality improvement. They recognised the need for data to be collected to support national efforts, and the fact that this is already mandatory. Due to the variation in adherence, they agreed to make an overarching recommendation in this area.

See table below for comments from SH's with disclosure on tobacco funding/links

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Novartis Pharmaceuticals UK	Guideline	005	001	This recommendation fails to include critical factors that should be considered when selecting SACT treatment for advanced breast cancer, which could lead to sub optimal decisions for patients that lead to poorer patient outcomes.	Thank you for your comment. The committee agreed that the benefits of a treatment would be taken into account in all decisions about choice of systemic anticancer therapy (SACT), and that these have also been taken into account in any assessments to decide what will be funded and available. For

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				The primary goals in treating advanced breast cancer are to extend progression-free survival (PFS) and overall survival (OS) while minimising toxicity. In order to make effective decisions about SACT treatment for advanced breast cancer, clinicians should perform a holistic, multidisciplinary assessment that considers a number of factors, including tumour biology, treatment efficacy, patient-specific factors, and quality of life. This section provides guidance about factors to consider when considering the use and selection of systemic anticancer therapy (SACT) for advanced breast cancer. We agree with the factors listed, however, there are critical missing factors relating to treatment efficacy which must also be included. We recommend that additional factors are added to the beginning of this section including demonstration via robust phase 3 clinical trials of progression-free survival and demonstration via robust phase 3 clinical trials of overall survival benefit. Failure to include these critical treatment efficacy considerations could lead to suboptimal selection of treatments, impacting delivery of improved patient outcomes.	completeness, the committee amended the recommendation about what factors to base the decision on to include the clinical benefits. They considered it to be too much detail to name specific outcomes in the recommendation itself.

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Novartis Pharmaceuticals UK	Guideline	009	001	This section signposts readers to NICE technology appraisal guidance for hormone-receptor-positive, HER2-negative advanced breast cancer. We welcome the addition of the links to the NICE technology appraisal guidance. Nonetheless, there are additional studies and study endpoints that have been published since the publication of many of the NICE TAGs that are linked in the guideline which provide further evidence about these medicines and demonstration of overall survival (OS), a critical parameter when selecting choice of treatment. It is important to find a way to include this additional evidence in the NICE guidelines so that clinicians are able to make the best selection of treatments to optimise patient outcomes. For example, ribociclib has demonstrated significant and consistent overall survival (OS) benefits in patients with hormone receptor-positive (HR+), HER2-negative (HER2-) metastatic breast cancer across various clinical trials. These include 3 studies published between 2019 and 2022:	Thank you for your comment. It was out of scope for technology appraisal (TA) incorporation to look at evidence not included in the TA submission. Please see the Interim process and methods statement for bringing together NICE guidance (PMG47) for more information about NICE's approach to including NICE technology appraisal recommendations in guideline topic areas. Any relevant studies published after the publication of this guideline will be picked up by the NICE surveillance team and will be considered for inclusion in future updates.

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				• First-Line Postmenopausal (MONALEESA-2): In patients receiving first-line ribociclib + letrozole, the median overall survival was 63.9 months compared to 51.4 months with placebo + letrozole, representing a significant 12.5-month improvement in median OS and a 24% reduction in the risk of death. See link to 2022 NEJM paper: Overall Survival with Ribociclib plus Letrozole in Advanced Breast Cancer | New England Journal of Medicine. • First-Line Pre/Perimenopausal (MONALEESA-7): Ribociclib plus endocrine therapy significantly improved OS in younger patients (median OS not reached in ribociclib arm vs 40.9 months with endocrine therapy alone). See link to 2019 NEJM paper: Overall Survival with Ribociclib plus Endocrine Therapy in Breast Cancer | New England Journal of Medicine. • Second-Line/Combination (MONALEESA-3): Studies in this population showed a median OS of 58.7 months with ribociclib versus 48.0 months with placebo. See 2019	

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				NEJM paper: Overall Survival with Ribociclib plus Fulvestrant in Advanced Breast Cancer | New England Journal of Medicine. Whilst NICE TA687 on Ribociclib with fulvestrant was published in March 2021 and includes data on overall survival, NICE TA496 on Ribociclib with an aromatase inhibitor was published in December 2017, before publication of two critical study endpoints demonstrating positive OS benefit. Palbociclib has failed to show a statistically significant improvement in overall survival in combination with letrozole and in combination with fulvestrant in advanced breast cancer in the PALOMA-2 and PALOMA-3 clinical trials: See link to JCO PALOMA-2 Study: Overall Survival With Palbociclib Plus Letrozole in Advanced Breast Cancer | Journal of Clinical Oncology, see link to NEJM PALOMA-3 study: Overall Survival with Palbociclib and Fulvestrant in Advanced Breast Cancer | New England Journal of Medicine. Abemaciclib demonstatrated a statistically signifincant improvement in overall survival in	

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				combination with fulvestrant (See link to JAMA MONARCH-2 study: The Effect of Abemaciclib Plus Fulvestrant on Overall Survival in Hormone Receptor–Positive, ERBB2-Negative Breast Cancer That Progressed on Endocrine Therapy—MONARCH 2: A Randomized Clinical Trial | Breast Cancer | JAMA Oncology | JAMA Network) However abemaciclib did not reach statistical significance for overall survival in combination with a non-steroidal aromatase inhibitor (See link to Ann. Oncol. MONARCH-3 study: Abemaciclib plus a nonsteroidal aromatase inhibitor as initial therapy for HR+, HER2− advanced breast cancer: final overall survival results of MONARCH 3 - ScienceDirect)	
Novartis Pharmaceuticals UK	Guideline	020	012	This section provides a short explanation of why the committee made the recommendation on systemic anticancer therapy for advanced breast cancer on pages 5 and 6. The committee set out to consider factors to select choice of treatment when selecting chemotherapy regimens for people with triple negative advanced breast cancer. The explanation notes that the committee concluded that the selected	Thank you for your comment. The committee agreed that the benefits of a treatment would be taken into account in all decisions about choice of systemic anticancer therapy (SACT), and that these have also been taken into account in any assessments to decide what will be funded and available. For completeness, the committee amended the recommendation about what factors to base the decision on to include the clinical benefits. They

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				factors applied to all receptor subtypes and all types of SACT. Whilst we agree that the factors listed are important considerations, as we outlined in our first comment, we believe that the recommendation fails to include critical treatment efficacy-based factors that should be considered when selecting SACT treatment for advanced breast cancer, and that the omission of these factors could lead to sub optimal decisions for patients and poorer patient outcomes. The primary goals in treating advanced breast cancer are to extend progression-free survival (PFS) and overall survival (OS) while minimising toxicity. Factors highlighted by the committee in this explanatory note, like patient preferences, previous side effects and previous tumour response are important considerations but should be listed alongside key factors including progression free survival and overall survival. Failure to include these critical treatment efficacy considerations could lead to suboptimal selection of treatments, impacting delivery of improved patient outcomes.	considered it to be too much detail to name specific outcomes in the recommendation itself.

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Organisation name – Stakeholder or respondent	Disclosure on tobacco funding / links	Comments/Action
Novartis Pharmaceuticals UK	1) Since April 2005, Novartis has exclusively licensed glycopyrronium bromide and certain intellectual property relating to its use and formulation from Vectura and its co-development partner, Sosei Heptares. The following inhaled medications are comprised of, or contain, glycopyrronium bromide: o Seebri® Breezhaler® (glycopyrronium bromide), used as a maintenance treatment for Chronic Obstructive Pulmonary Disease (COPD) o Ultibro® Breezhaler® (indacaterol/glycopyrronium bromide), used as a maintenance treatment for COPD o Enerzair® Breezhaler® (indacaterol/glycopyrronium bromide/mometasone furoate), used as a maintenance treatment for asthma uncontrolled with long-acting beta-agonist (LABA)/inhaled corticosteroid (ICS). Phillip Morris International (a tobacco company) acquired Vectura Group Limited (formerly Vectura Group plc). In Sep. 17, 2024– Vectura Fertin Pharma, Inc., an affiliate of Philip Morris International Inc. announced the sale of its subsidiary Vectura Group Ltd. (Vectura) to Molex Asia Holdings Ltd.	

	2) Novartis has been granted with an exclusive license from Japan Tobacco Inc. (JT) under JT patents on a world-wide basis for commercial rights to trametinib (Mekinist®; TMT212). Trametinib is a kinase inhibitor indicated as a single agent or in combination with dabrafenib for the treatment of several oncology indications. In 2015, as part of its purchase of oncology products from GlaxoSmithKline, Novartis obtained the worldwide exclusive rights granted by JT to develop, manufacture, and commercialize trametinib. JT retains co-promotion rights in Japan."	