National Cancer Control Programme

DRAFT Staging and Surveillance of Patients with Cutaneous Melanoma

Draft National Clinical Guideline

XXXXXXX 2023

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1 Clinical questions, evidence statements and recommendations

Clinical question 1

In patients with invasive cutaneous melanoma, who should have radiological staging investigations performed to detect metastases and what radiological imaging is recommended?

Quality of Evidence

A Cochrane systematic review (Dinnes et al., 2019), two meta-analyses (Rodriguez Rivera et al., 2014, Xing et al., 2011), a systematic review (Schröer-Günther et al., 2012), a randomised control trial (Long et al., 2022, Luke et al., 2022) and an international guideline (Gershenwald et al., 2017) addressed this clinical question.

The studies within the meta-analyses and systematic reviews are of low quality due to study design, small patient numbers and outdated study periods. Therefore, we cannot generalise findings on imaging modalities and operator experience to current practice. Evidence to address overall survival and influence of radiological imaging on patient management is lacking and there is little or no evidence comparing different imaging modalities.

Who should receive additional imaging as part as staging?

No high quality evidence was identified on which patients would benefit from additional imaging as part of staging. One systematic review did demonstrate that the diagnostic accuracy of PET-CT appears to increase with higher American Joint Committee on Cancer (AJCC) stages (Schröer-Günther et al., 2012).

There is currently uncertainty around radiological staging investigations for patients with stage IIB and stage IIC cutaneous melanoma as there is no strong evidence base to answer this question. Adjuvant treatment for patients with stage IIB and stage IIC cutaneous melanoma is evolving with a recent phase III trial demonstrating a benefit (Long et al., 2022, Luke et al., 2022). Pembrolizumab has been granted a licence extension in Europe for use in adjuvant immunotherapy in resected stage IIB and IIC melanoma patients (children over 12 years of age and adults). Furthermore, the Eight Edition of the American Joint Committee on Cancer (AJCC) melanoma staging system suggests that patients with stage IIB and IIC melanoma are at a higher risk of recurrence than patients with stage IIIA disease (Table 1) (Gershenwald et al., 2017).

Table 1 Melanoma-specific survival rates from the Eighth Edition International Melanoma Database (Gershenwald et al., 2017)

Stage	5- year melanoma-specific survival	10-year melanoma-specific survival
Stage IIB	87%	82%
Stage IIC	82%	75%
Stage IIIA	93%	88%

The Guideline Development Group therefore recommend radiological staging investigations in patients with stage IIB and IIC cutaneous melanoma. Furthermore, the Guideline Development Group agree there is a paucity of high quality evidence to address radiological staging in stage III melanoma patients, however they acknowledge the expected potential clinical benefit of staging in this cohort.

Radiological imaging for staging

In a Cochrane systematic review (Dinnes et al., 2019), six studies (n=492 people) exploring primary staging following a confirmed diagnosis of melanoma were identified. Two studies (Arrangoiz et al., 2012, Maubec et al., 2007) evaluating PET-CT in participants with melanomas > 4 mm in thickness found sensitivities for the detection of any metastases were 30% (95% CI 7% to 65%) to 47% (95% CI 29% to 65%), and specificities were 73% (95% CI 45% to 92%) to 88% (95% CI 68% to 97%). One small prospective study (Veit-Haibach et al., 2009) comparing CT with PET-CT for the detection of nodal metastases demonstrated no false positive results for either CT or PET-CT (specificity 100%, 95% CI 92% to 100%); however, sensitivity was higher for PET-CT (38%, 95% CI 14% to 68%) compared to CT (23%, 95% CI 5% to 54%). For the detection of distant metastases, two additional cases were detected with PET-CT (sensitivity 42%, 95% CI 15% to 72%) in comparison to CT (25%, 95% CI 5% to 57%) with no difference in specificity (93%, 95% CI 81% to 99%). No data for MRI were identified. Results for ultrasound in the detection of nodal metastases (2 studies) were highly variable and likely subject to bias (Dinnes et al., 2019).

In addition, an older meta-analysis (Xing et al., 2011) found that PET-CT had a higher sensitivity (80%, 95% CrI = 53% to 93%) and specificity (87%, 95% CrI = 54% to 97%) compared to CT (sensitivity 51%, 95% CrI =24%-76%, specificity 69%, 95% CrI =30%-92%) for staging of distant metastases.

It must be noted that no survival benefit of PET-CT over CT has been identified. In the absence of strong evidence, limited radiology resources, access, cost, risk of asymptomatic distant disease and patient factors the consensus of the Guideline Development Group is to recommend contrast enhanced CT (CE-CT) for patients with stage IIB and IIC and PET-CT for radiological staging of patients with stage III cutaneous melanoma and above.

Benefit and Harm

The overall benefits of radiological imaging include; the determination of prognostic information, stage and location of the tumour, identification of early metastaic disease, identification of clinically occult disease and guiding access to treatment.

The identification of benign incidental findings is a potential harm for both the patient and the health service. Incidential findings may cause increased anxiety for the patient and further unnecessary investigations including additional biopsies and radiation exposure. Investiagtion of some incidental findings can put pressure on the health service including the availability of radiology resources.

Radiation dose varies with imaging modality (Table 2). Increased exposure to radiation can cause greater harm in young people, pregnant women and patients with an underlying predisposition to cancer. Due to higher radiation exposure with CT and PET-CT in young people and pregnant women, whole body and brain MRI is recommended. However, whole body MRI is a more difficult experience for some patients compared to CT and PET-CT. Some experiences described by patients include feeling claustrophobic and anxious in the MRI machine, finding it difficult to remain still for the duration of the scan and finding the noise of the MRI machine disturbing.

Whole body PET-CT v CT-TAP

The benefits of whole body PET-CT compared with CT-TAP include a higher sensitivity for the detection of metastases, the ability to analyse metabolic activity and the ability for whole body

radiological imaging to be performed. The identification of small volume disease using PET-CT may also allow earlier initiation of treatment.

The potential harms of whole body PET-CT compared with CT-TAP include a higher incidence of false positive results and a more difficult experience for some patients. Some experiences described by patients include discomfort from the radiopharmaceutical injection prior to the scan, the long time spent in the machine and the inconvenience associated with having to travel long distances due to the limited availability of PET-CT scanners. Patients also need to avoid close contact with babies, young children and pregnant women for a number of hours following a PET-CT. The advantages of PET-CT in commencement of earlier therapy have to be weighed against the potential side-effects of therapy.

Brain scans

The benefits of a brain MRI scan include identification of more subtle disease compared with that of CE-CT. However, CE-CT brain scans can be performed in conjunction with a whole body CT. This has a cost and practicality benefit compared to PET-CT which requires a separate brain MRI scan.

Table 2 Typical effective doses for common procedures (The Royal College of Radiologists, 2022)

Diagnostic and interventional procedures	Typical effective dose (mSv)	Approximate equivalent period of exposure to background radiation*
Limbs and joints X-ray (except hips)	<0.01	<2 days
Chest X-ray (postanterior)	0.015	2 days
Lumbar spine X-ray	0.6	3 months
CT head	1.8	8 months
Coronary angiogram	3.9	1.4 years
CT pulmonary angiogram	9.7	3.6 years
CT abdomen & pelvis	13	4.8 years
CT chest abdomen pelvis	19	7 years
Radionuclide studies		
GFR (Tc-99m)	0.05	7 days
Bone (Tc-99m)	3	1.1 years
Cardiac SPECT (Tc-99m)	6.4	2.4 years
Whole body PET-CT (F-18-FDG)	18	6.7 years

*Calculations based on UK average from all sources = 2.7 milliseverts (mSv) per year: regional averages 1.5-7.5 mSv per year

Preferences and values

The multidisciplinary Guideline Development Group including patient representatives recognise knowledge as an important patient value.

The justification of why a patient is or is not having radiological staging investigations performed to detect metastases should be clearly communicated to the patient.

Communication around timelines, when results are available and how they will be communicated are important in managing patient's expectations and maintaining trust. It is also important that patients are informed of the benefits and harms including radiation exposure during radiological imaging. This means that the values of disclosure and understanding are embedded into patient/clinical communication. This has the benefit of reducing some of the patient's anxiety

around staging investigation results. It also reassures the patients that they are receiving care based on the best current evidence.
(Driving value- knowledge, trust)

Resources, capacity and other considerations

There was no relevant cost-effectiveness literature found to address this clinical question.

The following resources, capacity and other considerations were discussed in detail by the GDG:

Radiology resources

The Guideline Development Group highlighted that the expansion of radiological staging may require additional radiology resources. 1,227 malignant melanomas were diagnosed in Ireland in 2019 (National Cancer Registry Ireland (NCRI), 2023). Approximately 70% of malignant melanomas were stage IIA or less with 27% of melanomas falling into category IIB-IV. Previously based on NICE guidelines stage IIC with no sentinel lymph node biopsy (SLNB) and stage III and above were recommended to have radiological imaging as part of staging. If staging radiological imaging is extended to include earlier stages IIB (81 new cases per annum) and IIC (70 new cases per annum) an increase of less than approximately 151 extra patients nationally may be staged per annum based on NCRI incidence rates (NCRI, 2023).
Additional Clinical Nurse Specialists and Advanced Nurse Practitioners will also be required.

Equity

The Guideline Development Group highlighted that equity in staging investigations between patients and European countries is important.
Limited radiology resources can result in delays with extensive waiting lists and therefore inequity in access for patients.

Recommendation 1.1
In patients with stage IA cutaneous melanoma radiological imaging is not recommended, in the absence of signs and symptoms.

Quality of Evidence: Low **Grade of recommendation: Strong**

Recommendation 1.2
In patients with stage IB cutaneous melanoma radiological imaging is not recommended in the absence of signs and symptoms.

Quality of Evidence: Low **Grade of recommendation: Strong**

Recommendation 1.3
In patients with stage IIA cutaneous melanoma radiological imaging is not recommended in the absence of signs and symptoms.
Quality of Evidence: Low **Grade of recommendation: Strong**

Recommendation 1.4
In patients with stage IIB and stage IIC cutaneous melanoma staging with whole body and brain contrast enhanced CT (CE-CT) may be considered.
Quality of Evidence: Low **Grade of recommendation: Weak**

Recommendation 1.5
In patients with stage III and stage IV cutaneous melanoma staging with whole body PET-CT and brain MRI is recommended.
Quality of Evidence: Low **Grade of recommendation: Strong**

Recommendation 1.6
In children and young adults (from birth to 24 years) and pregnant women with stage IIB to IV melanoma, consider staging with whole body and brain MRI, instead of CT/PET-CT due to radiation risk.
Quality of Evidence: Low **Grade of recommendation: Strong**

Good practice points

- If PET-CT is not available due to local factors or other patient factors then CE-CT should be performed as an alternative.
- If the primary melanoma is on the head and neck and a CE-CT is performed for staging, a neck CT should be included.

Practical considerations around patient care

- All patients diagnosed with cutaneous melanoma should have timely access to a Clinical Nurse Specialist or Advanced Nurse Practitioner for communication around their diagnosis, staging, surveillance and timelines. The patient should be clearly informed of when staging results are available and how their results will be communicated.
- All patients diagnosed with cutaneous melanoma should have timely access to a Clinical Nurse Specialist or Advanced Nurse Practitioner to explain the benefits and harms of radiological imaging for staging and surveillance.
- All patients diagnosed with cutaneous melanoma should be given advice that is accurate and easy to understand on self skin examination, nodal basin examination and scar examination.

Clinical question 2

In patients with cutaneous melanoma who have completed treatment (surgical ± adjuvant treatment) what radiological surveillance imaging and at what interval should radiological surveillance be carried out to detect locoregional disease or distant metastases?

Quality of Evidence

A meta-analysis (Xing et al., 2011), systematic review (Schröer-Günther et al., 2012), randomised controlled trial (Moncrieff et al., 2022), retrospective study (Turner et al., 2021) and international guidelines (National Institute for Health and Care Excellence (NICE), 2022, Rajagopal, 2023, National Comprehensive Cancer Network (NCCN), 2023, Gershenwald et al., 2017) addressed this clinical question. Supporting evidence was also included from three randomised controlled trials (Long et al., 2022, Luke et al., 2022, Faries et al., 2017, Leiter et al., 2016). The quality of the evidence is low. There are no prospective randomised controlled trials specifically on radiological surveillance as these are difficult to construct due to ethical issues. Some of the literature is old and not applicable as the quality of CT imaging has improved since publication.

Radiological surveillance imaging

A meta-analysis from Xing and colleagues (2011), found that PET-CT had the highest sensitivity (86%, 95% CrI = 76% to 93%), specificity (91%, 95% CrI = 79% to 97%), and diagnostic odds ratio (67, 95% CrI = 20.42 to 229.7), compared to CT for surveillance of distant metastases. This was however based on older retrospective studies published between 1990 and 2009 and patient stage and treatment was unclear.

A retrospective study evaluating the diagnostic accuracy of follow-up surveillance imaging with CT or PET-CT in 332 patients with resected stage IIIA–D melanoma, found a sensitivity of 79% and specificity of 88% for the detection of distant metastases (Turner et al., 2021). There was evidence that CT had a significantly higher specificity compared with PET-CT, PET-CT had a higher sensitivity but this was not significant.

There is currently uncertainty around radiological surveillance for patients with stage IIB and stage IIC cutaneous melanoma as there is no strong evidence base to answer this question. Adjuvant treatment for patients with stage IIB and stage IIC cutaneous melanoma is evolving with a recent phase III trial demonstrating a benefit (Long et al., 2022, Luke et al., 2022). Pembrolizumab has been granted a licence extension in Europe for use in adjuvant immunotherapy in resected stage IIB and IIC melanoma patients (children over 12 years of age and adults). Furthermore, the Eight Edition of the American Joint Committee on Cancer (AJCC) melanoma staging system suggests that patients with stage IIB and IIC melanoma are at a higher risk of recurrence than patients with stage IIIA disease (Table 1) (Gershenwald et al., 2017). The Guideline Development Group therefore recommend radiological surveillance in this cohort.

Table 1 Melanoma-specific survival rates from the Eighth Edition International Melanoma Database (Gershenwald et al., 2017)

Stage	5- year melanoma-specific survival	10-year melanoma-specific survival
Stage IIB	87%	82%
Stage IIC	82%	75%
Stage IIIA	93%	88%

It must be noted that no survival benefit of radiological surveillance has been identified. Radiological surveillance in asymptomatic patients should only be recommended if it will change a patient's management if asymptomatic disease is radiologically identified.

Frequency of radiological surveillance

The MELFO (MELanoma FOllow-up) an international phase III randomised controlled trial compared an experimental low-intensity schedule against current national guidelines in participants with stage IB-IIC disease (Moncrieff et al., 2022). No participants received routine imaging. At 5 years, patients assigned to the reduced, stage-adjusted follow-up schedule reported no difference in levels of anxiety, cancer worry, and stress response symptoms, in addition to physical and mental health-related quality of life when compared with those assigned to the current national guidelines. This study also found no difference in any survival outcomes between the 2 study arms (disease-free survival: hazard ratio=1.00, 95% confidence interval: 0.49–2.07, P= 0.99).

The new category of stage IIID in the AJCC Eight edition identifies a subgroup of patients at higher risk of recurrence/death within stage III disease. Stage IIID 5 year melanoma-specific survival is 32% and 10 year is 24% compared with 69% and 60% respectively for stage IIIC melanoma. Therefore, the recommendation of increased frequency of surveillance for this subgroup is in line with frequency for stage IV resected disease also a group with high risk of recurrence/death (Gershenwald et al., 2017).

International guidelines included to address this clinical question (NICE, 2022, Rajagopal, 2023, NCCN, 2023) demonstrate a consistency in the type and frequency of radiological surveillance. Radiological surveillance is recommended from stage IIB to stage IV melanoma patients (NICE, 2022, Rajagopal, 2023, NCCN, 2023). NICE recommends whole-body and brain contrast-enhanced CT (CE-CT) scans, while Cancer Care Ontario 2023 and NCCN recommends CE-CT or PET-CT scans. Discharge at the end of year 5 is consistent across guidelines (NICE, 2022, Rajagopal, 2023, NCCN, 2023). In the absence of strong evidence, limited radiology resources and keeping in line with international guidelines, the consensus of the Guideline Development Group is to recommend CE-CT for stage IIB and IIC and PET-CT for radiological surveillance of stage III patients and above.

Additionally, based on DeCOG-SLT and MSLT-II trials, the Guideline Development Group agree that in circumstances where CE-CT or PET-CT is not being performed in patients with stage III positive sentinel lymph node cutaneous melanoma that have not had a complete lymph node dissection, ultrasound scans of the draining nodal basin should be considered (Faries et al., 2017, Leiter et al., 2016).

Benefit and Harm

The benefits of radiological surveillance include detecting recurrent asymptomatic disease which can enable access to treatment and provide reassurance to patients and to clinicans at that point in time. Capturing early disease may enhance treatment however there is no evidence to demonstrate that this improves outcomes.

The identificaiton of benign incidental findings is a potential harm for both the patient and the health service. Incidential findings may cause increased anxiety for the patient and further unnecessary investigations including additional biopsies and radiation exposure. In a study by Turner et al. 2021, evaluating surveillance imaging, false-positive findings generated a total of 684 further investigations, procedures, clinic visits, and referrals in 152 of 332 patients (46%). These further investigations generated more imaging studies and biopsies, with little additional benefit

to these patients. Investiagtion of some incidental findings can put pressure on the health service including the availability of radiology resources.

Radiation dose varies with imaging modality (Table 1). Increased exposure to radiation can cause greater harm in young people, pregnant women and patients with an underlying predisposition to cancer. Due to higher radiation exposure with CT and PET-CT in young people and pregnant women, whole body and brain MRI is recommended. However, whole body MRI is a more difficult experience for some patients compared to CT and PET-CT. Some experiences described by patients include feeling claustrophobic and anxious in the MRI machine, finding it difficult to remain still for the duration of the scan and finding the noise of the MRI machine disturbing.

Whole body PET-CT v CT-TAP

The benefits of whole body PET-CT compared with CT-TAP include a higher sensitivity for the detection of metastases, the ability to analyse metabolic activity and the ability for whole body radiological imaging to be performed. The identification of small volume disease using PET-CT may also allow earlier initiation of treatment.

The potential harms of whole body PET-CT compared with CT-TAP include a higher incidence of false positive results and a more difficult experience for some patients. Some experiences described by patients include discomfort from the radiopharmaceutical injection prior to the scan, the long time spent in the machine and the inconvenience associated with having to travel long distances due to the limited availability of PET-CT scanners. Patients also need to avoid close contact with babies, young children and pregnant women for a number of hours following a PET-CT. The advantages of PET-CT in commencement of earlier therapy have to be weighed against the potential side-effects of therapy.

Brain scans

The benefits of a brain MRI scan include identification of more subtle disease compared with that of CE-CT. However, CT brain scans can be performed in conjunction with a whole body CT. This has a cost and practicality benefit compared to PET-CT which requires a seperate brain MRI scan.

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*Calculations based on UK average from all sources = 2.7 milliseverts (mSv) per year: regional averages 1.5-7.5 mSv per year

Preferences and values

The multidisciplinary Guideline Development Group including patient representatives recognise knowledge and trust as important patient values.

The justification of why a patient is or is not having radiological surveillance performed to detect recurrence should be clearly communicated. The justification of the frequency of follow-up appointments should also be explained to the patient. This is important as a reduced number of follow-up appointments may cause anxiety and fear in some patients especially during the early stages after treatment when there are uncertainties surrounding the future of their condition. Similarily an increased number of follow-up appointments may cause cause anxiety and fear in some patients.

Communication around timelines, when results are available and how they will be communicated are important in managing patient's expectations and maintaining trust. It is also important that patients are informed of the benefits and harms including radiation exposure during radiological imaging. This means that the values of disclosure and understanding are embedded into patient/clinical communication. This has the benefit of reducing some of the patient anxiety around radiological surveillance results. It also reassures the patient that they are receiving the care based on the best current evidence.
(Driving value-knowledge, trust)

Resources, capacity and other considerations

There were no relevant cost-effectiveness literature found to address this clinical question.

The following resources, capacity and other considerations were discussed in detail by the Guideline Development Group:

Radiology resources

The Guideline Development Group highlighted the expansion of radiological surveillance may require additional radiology resources. 1,227 malignant melanomas were diagnosed in Ireland in 2019 (National Cancer Registry Ireland (NCRI), 2023). Approximatley 73% of malignant melanomas were stage IIA or less with 27% of melanomas falling into category IIB-IV. Previously based on NICE guidelines stage IIC with no sentinel lymph node biopsy (SLNB) and stage III and above were recommended to have radiological surveillance. If radiological surveillance is extended to include earlier stages IIB (81 new cases per annum) and IIC (70 new cases per annum) an increase of less than approximately 151 extra patients nationally may be included in radiological surveillance based on NCRI incidence rates (NCRI, 2023).
Additional Clinical Nurse Specialists and Advanced Nurse Practitioners will also be required.

Equity

The Guideline Development Group highlighted that equity in radiological surveillance between patients and European countries is important.
Limited radiology resources can result in delays with extensive waiting lists and therefore inequity in access for patients.

Recommendation 2.1
In patients with cutaneous melanoma in-situ radiological imaging is not recommended.

Quality of Evidence: Low **Grade of recommendation: Strong**

Recommendation 2.2
In patients with stage IA cutaneous melanoma routine imaging is not recommended in the absence of signs and symptoms.

Quality of Evidence: Low **Grade of recommendation: Strong**

Recommendation 2.3
In patients with stage IB cutaneous melanoma routine imaging is not recommended in the absence of signs and symptoms.

Quality of Evidence: Low **Grade of recommendation: Strong**

Recommendation 2.4
In patients with stage IIA cutaneous melanoma routine imaging is not recommended in the absence of signs and symptoms.

Quality of Evidence: Low **Grade of recommendation: Strong**

Recommendation 2.5
In patients with stage IIB and stage IIC cutaneous melanoma radiological imaging every 6 months for year 1 to year 3 and then yearly for year 4 and year 5 may be considered. Whole body and brain imaging should be performed using contrast enhanced CT (CE-CT).

Quality of Evidence: Low **Grade of recommendation: Weak**

Recommendation 2.6
In patients with stage III cutaneous melanoma radiological imaging every 6 months for year 1 to year 3 and then yearly for year 4 and year 5 should be considered. Radiological imaging should be performed using PET-CT and MRI brain.

Quality of Evidence: Low **Grade of recommendation: Strong**

Recommendation 2.7
In circumstances where contrast enhanced CT (CE-CT) or PET-CT is not being performed in patients with stage III positive sentinel lymph node cutaneous melanoma that have not had a complete lymph node dissection, ultrasound scans of the draining nodal basin should be considered every four to six months for years 1 to 3, and then every six months for years 4 to 5.

Quality of Evidence: Moderate **Grade of recommendation: Strong**

Recommendation 2.8
In patients with stage IIID and stage IV cutaneous melanoma, radiological imaging every 3 months for year 1 to year 3 and then 6 monthly for year 4 and year 5 is recommended. Radiological imaging should be performed using PET-CT and MRI brain.

Quality of Evidence: Low **Grade of recommendation: Strong**

Recommendation 2.9
In children and young adults (from birth to 24 years) and pregnant women with stage IIB to IV melanoma, consider radiological surveillance with whole body and brain MRI, instead of CT/PET-CT due to radiation risk.
Quality of Evidence: Low **Grade of recommendation: Strong**

Good practice points

- Radiological surveillance in asymptomatic patients should only be considered if the patient is suitable for treatment and if it will change the management of radiologically identified asymptomatic disease.
- If PET-CT is not available due to local factors or other patient factors then CE-CT should be performed as an alternative.
- If the primary melanoma is on the head and neck, a neck CT should be included.
- There should be clear communication between clinicians in follow-up imaging to avoid duplication.
- If the patient is receiving adjuvant treatment for asymptomatic resected disease, imaging should be done in accordance with treatment protocols whilst receiving treatment.

Practical considerations around patient care

- All patients diagnosed with cutaneous melanoma should have timely access to a Clinical Nurse Specialist or Advanced Nurse Practitioner for communication around their diagnosis, staging, surveillance and timelines. The patient should be clearly informed of when surveillance results are available and how their results will be communicated.
- All patients diagnosed with cutaneous melanoma should have timely access to a Clinical Nurse Specialist or Advanced Nurse Practitioner to explain the benefits and harms of radiological imaging for staging and surveillance.
- All patients diagnosed with cutaneous melanoma should be given advice that is accurate and easy to understand on self skin examination, nodal basin examination and scar examination.
- All patients diagnosed with cutaneous melanoma receiving radiological surveillance, should contact their Clinical Nurse Specialist if they develop any signs or symptoms in between surveillance scans.

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