Options for Stage III Melanoma
Making the Decision That’s Right for You

Companion Piece For Australian Patients

This is a companion piece for the guide, *Options for Stage III Melanoma: Making the Decision That’s Right for You*, which can be downloaded here (https://aimwithimmunotherapy.org/australia/).

This companion piece was developed based on the answers to questions posed by real patients who attended a Facebook Live review of the guide. We hope you find this information helpful as you navigate your way through your Stage III melanoma diagnosis.

A resource from the Melanoma International Patient Advocates Coalition. The content was created through a collaboration of AIM at Melanoma Foundation and Melanoma and Skin Cancer Advocacy Network (MSCAN, mscan.org.au).
Questions and Answers

What is stage III melanoma?

Stage III melanoma is melanoma that has spread (metastasised) from the primary tumour to the regional area. This is in contrast to melanoma that has spread far away to a distant location. In Stage III, melanoma has spread from the original location to the region right around it, or a little further toward the lymph nodes in the region, or to the regional lymph nodes.

You may be familiar with the lymph nodes in your neck, armpit, and groin, as highlighted in the diagram.

Graphic 17 shows a primary melanoma and regional metastases to the lymph nodes.

Guide Notes:
The last part of the guide contains an in-depth discussion of melanoma staging. Pages 26-27 explain regional (Stage III melanoma) in text and pictures under the heading NODAL CLASSIFICATION: N1 to N3.

The diagram on page 27 shows a primary melanoma and regional metastases to the lymph nodes.

Finally, the N classification includes evaluation of satellites, in-transit metastases, and microsatellites. While they may be labeled with different terms, these are all grouped together as in-transit regional metastases and are considered regional disease. They all represent small metastases that are close to but separate from the primary tumor. They have not reached the regional (nearby) lymph node.

You could also have other forms of regional (Stage III) disease. For example, an in-transit metastasis would show up somewhere in the little lymphatic channels that travel away from the primary tumour location but not quite as far as the lymph nodes in the armpit. It would also be Stage III disease if the melanoma spread to the area right around the original primary tumour. This type of spread is sometimes picked up when your doctor performs the wide local excision and is called a microsatellite.

So you may hear different terms—nodal disease, satellite, microsatellite, or in-transit disease—to describe melanoma that has spread in the region (Stage III disease).

Questions and Answers
Why should I know what specific subgroup of Stage III melanoma I have?

Stage III melanoma encompasses a wide range of conditions. You may have only one or multiple lymph nodes that contain cancer. Your lymph nodes may be enlarged to the point that your doctor can see or feel them. Or the affected lymph nodes may not be readily apparent—they may only have been detected when the lymph node was biopsied, and the cancer was visible under the microscope. It could be that you had matted or clumped lymph nodes. Alternatively, you may have melanoma in any clumped nodes plus in-transit, satellite, or microsatellite metastases visible or palpable (detected by SLN biopsy) or 1 node found, not visible or palpable (detected by SLN biopsy).

Guide Notes: In addition to pages 26 and 27 of the guide, which explain all of the GLIIHUHQWHOHPHQWVRWKHQGDOFODVV system, page 29 contains a table that helps you understand how the primary tumour characteristics and the nodal characteristics can be used to determine your stage. The table also shows the 5-year and 10-year survival rates associated with each subgroup at the time that the staging system was published.

Your doctor can use this table to help you understand how he/she arrived at your stage and what it means for the predicted course of your disease (prognosis). However, it is important to remember that survival differs with each subgroup. Stage IIIA, IIIB, IIIC, or IIID. The prognosis differs with each subgroup.
Why is surgery sometimes not enough?

Surgery for stage III disease is sometimes not enough. In Stage III patients, the risk of the disease coming back (recurring) can be high enough that surgical removal of the tumour(s) is not enough. When a lymph node is positive, the melanoma can have access to the rest of the body. It can spread throughout the lymphatic system. The lymphatic system is closely tied to the bloodstream, which travels everywhere throughout the body. So even though the melanoma may have started on your hand, if it gets into the lymphatics, it can spread more easily. Overall, Stage III patients have about a two-thirds chance of recurrence over 5 years. Thus, there can be a strong rationale for taking medication to prevent the disease from coming back. The higher your stage of Stage III, the greater the risk of recurrence from the disease.

Guide Notes: On pages 2-4, the guide addresses the risk for recurrence with Stage III melanoma. It shows survival curves that help you understand why Stage III melanoma is considered high risk and how the risk increases with progressive substages (Stage IIIA, Stage IIIB, Stage IIIC, Stage IIID). It also explains how the tumour can come back even when the surgeon removed all the visible tumour.

UNDERSTANDING YOUR RISK

Your melanoma stage affects the expected course of your disease. The stages of melanoma are generally divided into 4 groups:

- **Stage 0** is melanoma that has not penetrated through the deepest layers of the skin or lymph nodes.
- **Stage I** is melanoma that has penetrated through the deepest layers of the skin or lymph nodes.
- **Stage II** is melanoma that has spread to the lymph nodes or to the nearby skin/tissue in between. Stage II melanoma is divided into 3 substages (A, B, and C), as described below. For more information about how these substages are defined, see the section further reading on stage II melanoma.
- **Stage III** is melanoma that has spread farther than regional lymph nodes, to distant sites throughout the body. So even though the melanoma may have started on your hand, if it gets into the lymphatics, it can spread more easily. Overall, Stage III patients have about a two-thirds chance of recurrence over 5 years. Thus, there can be a strong rationale for taking medication to prevent the disease from coming back. The higher your stage of Stage III, the greater the risk of recurrence from the disease.

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**WHY ARE STAGE III PATIENTS AT HIGH RISK FOR RECURRENT, AND WHY SHOULD THEY CONSIDER TREATMENT?**

High-risk melanoma is a melanoma that has a high likelihood of recurring or spreading after surgical treatment. Melanomas that are considered high risk are those that have spread beyond the original site of the melanoma, such as to regional lymph nodes, or beyond the regional lymph nodes but not to distant sites. These melanomas vary in how thick they are and whether the skin covering the melanoma is ulcerated or not. Thicker melanomas are of a different type. In some cases, it is difficult to predict the survival of a patient with Stage III melanoma. Survival rates are estimated averages based on past cases but do not necessarily predict your individual survival. Every person and case are different, and many factors contribute to survival. You can discuss these curves with your oncology team.

**Recurrence:** Recurrence of a melanoma is defined as the reappearance of a melanoma after treatment. Prior to the AJCC 8th edition, melanoma recurrence was defined as the reappearance of a melanoma after surgical treatment, or after local or systemic therapy, if specified in the AJCC staging system. In the AJCC 8th edition, melanoma recurrence is defined as the reappearance of a melanoma after treatment, whether surgical, medical, or a combination of both. The AJCC 8th edition also clarifies that the term “recurrence” can refer to the reappearance of any type of melanoma, regardless of the stage at diagnosis.

**Shedding light on Stage III Melanoma:** Within the Stage III group, survival rates generally get worse as you go from Stage III A to Stage III D. This is why it is important that you and your oncology team discuss your individual stage risk.

**Graphic 1:** Differences across AJCC staging. Source: © 2021 AIM at Melanoma Foundation and Terranova Medica, LLC. All Rights Reserved. Document Revised on March 13, 2021

<table>
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<th>Stage III mel</th>
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**Graphic 2:** Differences across AJCC staging. Source: © 2021 AIM at Melanoma Foundation and Terranova Medica, LLC. All Rights Reserved. Document Revised on March 13, 2021

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**Graphic 3:** Differences across AJCC staging. Source: © 2021 AIM at Melanoma Foundation and Terranova Medica, LLC. All Rights Reserved. Document Revised on March 13, 2021

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**Graphic 4:** Differences across AJCC staging. Source: © 2021 AIM at Melanoma Foundation and Terranova Medica, LLC. All Rights Reserved. Document Revised on March 13, 2021

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What do I need to know before I go to the oncologist?

There are a few pieces of information that your oncology team will need in order to evaluate the options to treat your high-risk melanoma.

First, the team needs all the details about your stage—this can include the pathology report from the original primary as well as all the information from the assessment of your lymph nodes (example, sentinel lymph node biopsy, surgery, needle biopsy, etc.). They will also need staging scans (imaging) to make sure that the melanoma has not already metastasised further, meaning it has spread past the lymph nodes to other parts of the body such as in the lung, liver, or bone. Such staging scans could include the use of a positron emission tomography/computer tomography (PET/CT) combination scan, magnetic resonance imaging (MRI), or a CT scan alone. If there are distant metastases, then you may be staged as Stage IV and you and your oncologist would then discuss therapy options specific to that stage.

Another important piece of the puzzle is your BRAF status. BRAF is a mutation that is present in approximately 50% of cutaneous (skin) melanomas that are tested. If you have melanoma on your hands/feet, your mucosa, or in your eye, different mutations can be involved—we will not be discussing options that are only available for patients with these subtypes.

Testing for the BRAF mutation is an option for you, you will need to have your tumor tested, even if your tumor has already been resected. BRAF mutation testing is an important part of your selection for one of the targeted therapies. If your tumor has not the BRAF mutation, you are not eligible for targeted therapy. But if your tumor does have the BRAF mutation, you are eligible for targeted therapy. Each of these options is discussed below, with a review of the potential pros and cons.

OPTIONS FOR STAGE III MELANOMA

You will now be working with your oncology team to figure out what to do next. There are several stages to this process.

1. Options for Stage III Melanoma
2. Targeted Therapy
3. Immunotherapy
4. Observation

Each of these options is discussed below, with a review of the potential pros and cons.

KEY TERMS:

BRAF: a gene that codes for a protein in the cell's protein production system. BRAF is essential for melanoma cells to grow. About half of all melanoma patients have a mutation in this gene. This is called having a BRAF mutation. Tafinlar® (dabrafenib) and Mekinist® (trametinib) are approved for adjuvant therapy for completely resected Stage IIIB, IIIC, and IIID melanoma.

Tafinlar + Mekinist is approved for patients with Stage IIIB, IIIC, and IIID melanoma that has been surgically removed and has been tested positive for the BRAF mutation. It is not approved for patients who do not have the BRAF mutation. It is not approved for patients who do not have the BRAF mutation. It is not approved for patients who do not have the BRAF mutation. It is not approved for patients who do not have the BRAF mutation. It is not approved for patients who do not have the BRAF mutation.

Targeted therapy uses medications that are designed to “target” your body’s own immune system to help fight any remaining cancer cells. You are eligible for targeted therapy if your tumor does not have the BRAF mutation, you are eligible for targeted therapy.

Immuno-oncology is a treatment that gives your immune system more power to fight your cancer. Every day, our immune system recognises dangerous things—cancer cells, foreign invaders like bacteria and viruses—and quickly stops them from doing damage. However, cancer cells have ways of evading the immune system, which means that some cancers can multiply and spread.

Observation is an option for patients who are not eligible for targeted therapy or immunotherapy. This means that your melanoma does not have the BRAF mutation. You should speak with your oncologist to ensure this takes place. If your melanoma does not have the BRAF mutation, you may not have ordered the test. You should ask to be tested for the BRAF mutation. Testing for the BRAF mutation requires that a sample of your melanoma tumor be processed in a specific way. Ideally, your melanoma should be resected for the BRAF mutation. You should speak with your oncologist to ensure this takes place.

To be tested for the BRAF mutation, you will need to have your tumor resected. This will be done as an outpatient. You do not need to be awake during the procedure. You should discuss your options with your oncologist. Occasionally, there is not enough tumor available to complete the test. If this happens, your oncologist will discuss what happens next. Immunotherapy may be more effective at treating melanomas that have the BRAF mutation.
What are the options for Stage III melanoma?

There are three options for managing Stage III melanoma: targeted therapy, immunotherapy, and active surveillance. Each are briefly discussed below.

Targeted therapy is a combination of oral medications—a BRAF/MEK inhibitor combination that can be used in patients who have the BRAF mutation. Together, these drugs block key protein enzymes that help the melanoma grow.

Another option is called active surveillance. With active surveillance you are not taking any medicine to prevent the melanoma from coming back, but you are keeping a close eye out for any recurrence. You would go back to your oncologist on a regular basis for monitoring, which would include examination of your skin, a clinical examination to feel for lymph nodes, and additional imaging scans to see if the melanoma has spread further. You might consider active surveillance if you and your oncologist feel like your risk for recurrence is relatively low or if the adjuvant medications are not good options for you.

Guide Notes:
The guide provides a detailed discussion of the options for stage III melanoma on pages 5-10.
How long is drug treatment?

The duration of therapy or treatment is one year. Treatment may be stopped if any side effects are noted by your treating team as early as possible so they can be best managed.

If the melanoma returns while on treatment, it will be important to discuss other treatment options with your treating team.

Do the drug treatments work?

These drugs are effective at reducing your risk of recurrence and improving survival rates in melanoma patients. We are continuously exploring new options for Stage III melanoma.

**Guide Notes:** See page 17 for a discussion of the how the drugs are given.

### HOW WELL THESE MEDICATIONS WORK

Drugs have different ways of working, how well they work, and their medications that work to help stop the spread and keep it in check, whether the cancer has come back or not. The other way is to look at whether these cancer treatments cure the cancer. The other way is to look at whether these cancer treatments cure the cancer. It's important to know that targeted therapy has not been compared directly (head-to-head) with immunotherapy in melanoma patients. We are continuously exploring new options for Stage III melanoma.

### MEDICATION ADMINISTRATION

For targeted therapy, you will be taking capsules/tabs/a day as long as you are tolerating the combination and the melanoma doesn't come back, for up to 1 year. Opdivo is given as an intravenous (IV) infusion into your arm, typically at your treating hospital. The medication is usually given every 2 weeks but can be given every 4 weeks and will be continued as long as you tolerate it and the melanoma doesn't come back, for up to 1 year. The infusion lasts for 30 minutes.

**Keytruda**

For Keytruda, the trial compared Keytruda with Yervoy. This trial enrolled 1,019 patients who had melanoma in their lymph nodes (Stage III, but excluding Stage IIIa) or distant metastases (Stage IV). The melanoma was surgically removed and who are at high risk of recurrence. Adapted from Weber et al. 2018. As shown in Graphic 5, after 18 months, 66% of the patients treated with Keytruda were melanoma free, compared with 53% of patients receiving Yervoy. Overall, there was an improvement in overall survival with Keytruda as compared with Yervoy.

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### OTHER CONSIDERATIONS

**DECISION-MAKING POINTS:**

- If you have stage III melanoma, you may be eligible for either targeted therapy or immunotherapy. The decision is yours. We don’t know if it is better for Stage III patients to receive targeted therapy or immunotherapy.
- For both targeted therapy and targeted therapy, we don’t yet know which patients will respond to the treatment and which won’t.
- Both Options and Keytruda are now available and listed on the PBS for subsidised access.

**IMMUNOTHERAPY**

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**TARGETED THERAPY**

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**Conclusions:**

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What are the side effects of these drugs?

It's important to understand that the side effects of these medications can be quite broad and can impact almost any part of the body. As mentioned earlier, immunotherapy works by unleashing the body's immune system to fight cancer, but this can also cause the body to react in unusual ways.

Inflammation, endocrine problems, pulmonary issues, etc. These can happen any time during the course of treatment. Other side effects as described in the guide. Your oncologist can adjust the medicine and reduce the dose if some of these side effects tend to be more severe. Once you are off therapy, these side effects subside altogether.

With immunotherapy, the most common side effect is fatigue. The drugs work by revving up the immune system to fight cancer, which can cause the body to react in unusual ways. It's best to treat them early. Sometimes these side effects can be managed with specific interventions. Other times, these side effects can be managed with either a decrease in the dosage or by briefly stopping one or both of the medications and then resuming the medication(s) after a few days.

With targeted therapy, sometimes an individual side effect can be managed with specific interventions. Other times, these side effects can be managed with decreasing the dosage. In some rare cases, the medication may need to be permanently discontinued. The following are the common side effects associated with targeted therapy and immunotherapy.

Options for Stage III Melanoma: Making the Decision That's Right for You

Guide Notes: See pages 11-16 for a discussion of the side effects of the drugs.
Will these drugs affect my ability to have children?

These drugs may cause fetal harm. Therefore, the general recommendation is for couples to avoid pregnancy while one of them is taking any of these medicines—whether it’s a man or a woman. So while you’re on therapy, make sure that you’re using two birth control methods. These can be condoms, female contraceptive, whatever that is for you. However, if you are a woman taking targeted therapy, you need to be careful with oral contraceptives because they may interact with immunotherapies. These medications may affect the hormone system long term because of a potential hormonal effect, so some patients have described difficulty getting pregnant for the year or so after they stopped treatment.

Most clinics will tell you not to conceive until at least six months after immunotherapy is stopped. Now, targeted therapy clears from your system a little bit faster, and the manufacture recommends that you don’t get pregnant for at least 4 months after therapy.

Before considering any next steps in family planning, consult your health care team.

Guide Notes: See page 19 for a discussion of fertility/family planning with these therapies.
Is one approach better than the other?

Not necessarily. Your oncologist will work with you on deciding your specific treatment plan. A lot of factors will be considered:

- Your substage and risk for recurrence
- Your BRAF status
- Any existing autoimmune conditions
- Your overall health
- The side-effect profile of the drugs
- Convenience/quality of life
- Fertility/Family planning

Guide Notes: See pages 20-22 for the worksheets to help you weigh your options. You can complete these worksheets with your healthcare team to evaluate the options and select the approach that is best for you.

The development of this companion piece was supported by an unrestricted educational grant from Bristol Myers Squibb.