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/uk/).

This companion piece was developed based on the answers to questions posed by real patients who attended a Facebook Live review of the guide. The content of this companion piece has been customized for the United Kingdom audience based on the input of Melanoma UK. We hope you find this information helpful to you as you navigate your way through your Stage III melanoma diagnosis.
What is stage III melanoma?

Stage III melanoma is melanoma that has spread (metastasized) 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 an example, let’s say you had a primary melanoma on your upper arm. The lymph nodes that the melanoma would typically travel to first would be under the armpit. If those tested positive for melanoma, it would be considered Stage III disease. 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).

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 N (nodal classification).
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 healthcare provider 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 the region between the primary tumour location and the lymph nodes. Your specific subgroup of Stage III melanoma is also affected by the characteristics of your primary melanoma—how thick it was and whether or not it was ulcerated, which means part of the upper layer of skin is broken on the top of the melanoma. Ulcerated melanomas have a different disease course (prognosis) than nonulcerated melanomas.

It's important to know this information and which subgroup of Stage III disease you have, whether it is Stage IIIA, IIIB, IIIC, or IIID. The prognosis differs with each subgroup.

### Table: Stage III Melanoma Substaging Criteria

#### Tumor, T Category with Thickness,

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Thickness</th>
<th>Ulceration</th>
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</thead>
<tbody>
<tr>
<td>T1a-T3a</td>
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<td>OR</td>
</tr>
<tr>
<td>T4a</td>
<td>More than 4.0 mm, ulcerated</td>
<td>OR</td>
</tr>
<tr>
<td>T4b</td>
<td>More than 4.0 mm, not ulcerated</td>
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#### Nodal Category

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<td>Stage IA</td>
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#### Stage IIIB

<table>
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<th>Nodal Category</th>
<th>Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any N1, N2, or N3 (any nodal involvement or in-transit, satellite, or microsatellite metastases)</td>
<td>Stage IIIB</td>
</tr>
</tbody>
</table>

### Guide Notes

- It's important to know this information and which subgroup of Stage III disease you have, whether it is Stage IIIA, IIIB, IIIC, or IIID. The prognosis differs with each subgroup.
- Your healthcare provider can use this table to help you understand how he/she arrived at your substage and what it means for the predicted course of your disease (prognosis). However, it is important to remember that survival rates do not predict an individual's outcome. Every person and every case are different, and many factors contribute to an individual's survival.
- It's also important to remember that new and successful treatments have emerged over the last few years, and survival rates are increasing in Stage III melanoma.

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*XLGH1RWHV In addition to pages 26 and 27 of the guide, which explain all of the different elements of the nodal classification 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 substage. The table also shows the 5-year and 10-year survival rates associated with each substage at the time that the staging system was published.*
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.

**UNDERSTANDING YOUR RISK**

Melanoma is a type of skin cancer that arises from melanocytes, the pigment-producing cells located in the body. Melanomas can spread to the lymph nodes (Stage I), to the nearby skin/tissue in between (Stage II), and to the lymph nodes, lung, liver, or brain (Stage III). Stage I melanoma is melanoma which has not penetrated (invaded) the deeper layers of the skin (in situ). Stage II melanoma is the melanoma that is confined to the lymph nodes and sometimes to the nearby skin/tissue. Stage III melanoma is melanoma that has spread farther than regional lymph nodes, to distant sites such as the lung, liver, or brain.

High-risk melanoma is a melanoma that has a high likelihood of recurring or spreading after the primary tumor has been surgically removed (staged). Patients with high-risk melanoma have a higher risk of their melanoma recurring within a shorter period. That means 2 out of 3 people will have a recurrence of their melanoma within 5 years of surgery. Stage III patients should consider adjuvant (additional) treatment.

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The idea that your cancer might come back is a loss that can be confusing to you, since you may have told yourself, "but I’m cured!” Nothing can be done to remove the disease that is inside your body. It is not possible to remove every single cell that went inside your body.

Your substage of Stage III tells you about your likelihood of the disease coming back (recurring) and staying away for a longer period of time. 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.

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

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**SHOULD THEY CONSIDER TREATMENT?**

Recently, a German study from the Central German and Pediatric Registry (ZGEP) evaluated survival rates for 1,535 patients with a Stage I melanoma diagnosis from 2001-2012. The investigators found that patients who received surgery in this group and other European groups, as compared with those reported by the AJCC, were lower. For example, in the ZGEP vs the AJCC group, 5-year survival for Stage I was 95% vs 99% for Stage I. Similar results were seen for 10-year survival and Stage III in general and in the more advanced substage.

Within the Stage III group, survival rates generally get worse as you go from Stage IIIA to Stage IIID. This is why it is important you and your oncology team discuss your individual stage and risk.

**Questions and Answers**

Your melanoma stage affects the expected course of your disease. The stages of melanoma can be divided into 4 main groups, A, B, C, and D, as described below. For more information about how these groups are defined, please see your oncology team.

**Stage 0** is melanoma which has not penetrated (invaded) the deeper layers of the skin (in situ).

**Stage I** is melanoma that are limited to the skin. These melanomas vary in how thick they are and whether the skin covering the melanoma is normal or not. Thinner melanomas and ulcerated melanomas have a higher risk of recurring.

**Stage II** is melanoma that has spread from the original site of the melanoma to 1 or more of the nearby lymph nodes and/or to the lymph node drainage area beneath the melanoma.

**Stage III** is melanoma that has spread farther than regional lymph nodes, to distant sites such as the lung, liver, or brain.

A survival curve shows how many people can be expected to still be alive, typically anywhere from 1 to 10 years, after their diagnosis. Graphics 1 & 2 show the likelihood of surviving melanoma for 5 and 10 years, respectively, for different stages.

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**Stage 0**

Your survival is considered to be excellent. We do not typically recommend treatment for Stage 0 melanoma. You should consider a close follow-up with your oncology team.

**Stage I**

Stage IA has a 98% 5-year survival and a 99% 10-year survival. Stage IB has a 97% 5-year survival and a 98% 10-year survival. For Stage IC, 5-year survival is 95% and 10-year survival is 97%.

**Stage II**

Stage IIA has a 95% 5-year survival and a 97% 10-year survival. Stage IIB has a 94% 5-year survival and a 96% 10-year survival. Stage IIC has a 92% 5-year survival and a 95% 10-year survival.

**Stage III**

Stage IIIA has a 90% 5-year survival and a 91% 10-year survival. Stage IIIB has a 88% 5-year survival and a 90% 10-year survival. Stage IIIC has a 85% 5-year survival and a 88% 10-year survival.

Within the Stage III group, survival rates generally get worse as you go from Stage IIIA to Stage IIID. This is why it is important you and your oncology team discuss your individual stage and risk.
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 node (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 metastasized farther, 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 would be staged as Stage IV and you and your oncologist would then discuss therapy options specific for 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 those types of melanoma in this guide. For cutaneous melanoma, the reason it’s important to know your **BRAF** status is that there are drug treatments, BRAF/MEK inhibitor combinations, that are an option for adjuvant therapy if you have the **BRAF** mutation. But those drugs don’t work if you don’t have the **BRAF** mutation.

To be tested for the **BRAF** mutation, your pathologist, surgeon, dermatologist, or oncologist must order the test. If your healthcare provider has not ordered the test, you will want to talk with either your surgeon, dermatologist, or oncologist about ordering it. If your healthcare provider has already ordered the test, you will want to talk with either your surgeon, dermatologist, or oncologist about discussing the results.

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

To be tested for the **BRAF** mutation, you will need to provide a sample of your melanoma tumor that contains DNA. This can be achieved in a number of ways:

1. **Surgically removed melanoma**
   - The pathologist must test the sample for the **BRAF** mutation.
   - It is important to know your **BRAF** mutation status before sitting down with your oncologist to discuss your options.

2. **Biopsy**
   - A **biopsy** is a small sample of tissue that can be obtained from the primary tumor or from any metastatic lesion. This is typically done during a visit to your dermatologist or surgeon.
   - **Biopsies** can help determine your eligibility for targeted therapy.

   Remember, these drugs only work in people who have the **BRAF** mutation. Both **BRAF** inhibitors and MEK inhibitors are key protein enzymes that help melanoma cells grow. About half of all melanoma patients have a mutated form of the **BRAF** gene in their tumors. This is called having a **BRAF** mutation.

   For those patients with a **BRAF** mutation, there is an option to use a combination of a **BRAF** inhibitor and a MEK inhibitor. These drugs work by blocking these proteins and proteins involved with them to stop the **BRAF** mutation from spreading. When used together, these drugs can help control the melanoma growth.

   You will want to discuss the **BRAF** mutation with your oncology team in order to catch your melanoma early if it comes back.

   Targeted therapy is now available for patients with Stage III melanoma that has been surgically removed and has tested positive for the **BRAF** mutation. It is not approved for patients who do not have the **BRAF** mutation (and hence the **BRAF** mutation status is critical before choosing a treatment).

   The second option is immunotherapy. Immunotherapy uses medications designed to help turn on your body’s immune system to help fight and stop the growing cancer cells. You can have either a **BRAF** mutation or no mutation and still be eligible for immunotherapy. Both will help fight your cancer in different ways—**BRAF** mutation-positive tumors respond to **BRAF** inhibitors and MEK inhibitors, while **BRAF** mutation-negative tumors respond to **PD-1** inhibitors. So there is no one-size-fits-all option for melanoma. You and your oncologist will discuss what works best for you.

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

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   The guide provides a discussion of **BRAF** testing and treatment for **BRAF**-positive melanoma (pages 5-6).

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**OPTIONS FOR STAGE III MELANOMA**

You will now be working with your oncology team to figure out what to do next. There are a few options if you have Stage III melanoma. There are targeted therapy, chemotherapy, or active surveillance (no medication involved).

1. **Targeted Therapy**
   - **Dabrafenib + trametinib** is approved for patients with Stage III melanoma that has been surgically removed and has tested positive for the **BRAF** mutation. It is not approved for patients who do not have the **BRAF** mutation (and hence the **BRAF** mutation status is critical before choosing a treatment).
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2. **Immunotherapy**
   - **Ipilimumab** is a **PD-1** inhibitor approved for adjuvant therapy as well. It is approved for patients with Stage III melanoma and can be used in combination with **BRAF** inhibitors or **MEK** inhibitors. It is effective for patients with Stage III melanoma with a well-accepted test to ensure that your healthcare team has access to the information needed to make the right decision.

   **BRAF** mutations require that a sample of your melanoma tumor be tested for the **BRAF** mutation before sitting down with your oncologist to discuss your options. Occasionally, there is not enough tumor available to complete the test. If this happens, your oncologist will discuss what happens next. Oncology teams have become more adept at handling these challenging situations with more experience and testing options.

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**IMMUNOTHERAPY**

**Immunotherapy** is a treatment that gives your immune system more power to fight your cancer. Every day, our immune system recognizes dangerous things—cancer cells, foreign invaders like bacteria and some viruses—and this is the way our body keeps itself healthy. However, some cancer cells (including some melanomas) will try to evade your immune system by using different mechanisms to prevent it from attacking the disease. Antibodies that are designed to block these mechanisms can help turn on your immune system and fight the cancer on its own. **Ipilimumab** is a **PD-1** inhibitor approved for adjuvant therapy as well. It is approved for patients with Stage III melanoma and can be used in combination with **BRAF** inhibitors or **MEK** inhibitors. It is effective for patients with Stage III melanoma with a well-accepted test to ensure that your healthcare team has access to the information needed to make the right decision.

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May 3, 2021

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. Immunotherapy treatments give your immune system more power to fight cancer. Currently, immune checkpoint inhibitors—PD-1 inhibitors and CTLA4 inhibitors—are used as adjuvant immunotherapy for melanoma.

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.
Targeted therapies and PD-1 inhibitors can be given for up to a year—as long as you tolerate the side effects and the melanoma has not come back.

These drugs are effective at reducing your risk of recurrence and improving survival rates in melanoma patients. We are continuously learning about the long-term benefits of these drugs on survival.

**How Well Do the Drugs Work?**

Doctors have different ways of thinking about how well cancer drugs work. First, they typically look at how many people are still alive after 5 years and after 10 years. This is called overall survival. Benefit is long-lasting when patients who are disease-free continue to live for a long time after treatment. Benefit may also be measured as time to recurrence (time to relapse).

**Targeted Therapy**

For targeted therapy, a trial compared the combination of dabrafenib and trametinib with a placebo. At 3 years, 64% of patients treated with the combination were still melanoma free, compared with 41% of patients receiving the placebo. Overall, there was a 35% reduction in the risk of melanoma coming back in patients treated with the combination as compared to the placebo.

**Immunotherapy**

For immunotherapy, a trial compared nivolumab with ipilimumab. At a 4-year follow-up, 62% of patients treated with nivolumab were melanoma free, compared with 46% of patients receiving ipilimumab. Overall, there was a 27% reduction in the risk of melanoma coming back in patients treated with nivolumab as compared to ipilimumab.

**DECISION-MAKING POINTS:**

- **PD-1 inhibitors:** You may be eligible for either targeted therapy or immunotherapy. We don’t know if it is better for Stage III patients to receive targeted therapy and PD-1 inhibitors or immunotherapy alone.
- **For both immunotherapy and targeted therapy, we do not know which patients will respond well to these drugs and which ones won’t.**
- **It is important not to come to the snap judgment of the data we have given you and try to compare the treatments. These trials were done in different groups of people at different times, and the results are not replicable. We’re also only telling you part of the story, so it is important to make a decision coming from your own perspective and not the material you have just learned.
Options for Stage III Melanoma: Making the Decision That's Right for You

Companion Piece for Patients in the United Kingdom.

Questions and Answers

With the BRAF/MEK inhibitors, about 97% of patients will have some kind of side effect. So although it's easy to take this combination at home, you may experience side effects of some kind. The most common are fevers—and they can be pretty high, in the 103°F range; fatigue; and nausea. An itchy rash can develop. 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.

With immunotherapy, the most common side effect is fatigue. The drugs work by revving up the immune system, so you can develop autoimmune problems, like an inflammation of the colon, a rash, liver inflammation, endocrine problems, pulmonary issues, etc. These can happen any time during the course of your therapy or even after your therapy, and they can progress and become serious. But they can generally be treated quite effectively. So it's important to inform your care team about any changes in how you feel because some of the immune-related side effects can start off very subtly. It's best to treat them early.

See pages 11-16 for a discussion of the side effects of the drugs.
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 your medicine. While experts don’t believe these drugs have a direct long-term effect on fertility, the immunotherapies 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 four months after therapy.

Before considering any next steps in family planning, consult your health care team.
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 safety of the drugs
- Conveniences/quality of life
- Fertility/Family planning

Guide Notes: See pages 20-21 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.

### Worksheet 1: Targeted Therapy

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<thead>
<tr>
<th>Factor to Consider</th>
<th>My Thoughts</th>
<th>Weighting of Factor to You</th>
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### Worksheet 2: Immunotherapy

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### Worksheet 3: Active Surveillance

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Final Thoughts

We hope you found this guide to be helpful in evaluating your options for your Stage III melanoma. Our goal has been to empower you to work with your oncology team to make the best decisions for you. We have included the information in this guide so that you can consult it as you evaluate your options. Being informed puts you in the best position to have an active role in your important decision.

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