

## **What to Expect with Dinutuximab**

Coming at the end of an already long cancer treatment and having a very different short-term side effect profile than prior treatments, the start of dinutuximab therapy can feel like a whole new experience for most neuroblastoma families. The purpose of this chapter is to provide a general summary of dinutuximab treatment—why it is important, how it works, and what to expect. It contains information from families who have already experienced it so that patients and families embarking on the treatment can have some idea about what lies ahead.

### **We have done so much treatment already—why do we need antibody therapy too?**

The addition of antibody therapy with dinutuximab to standard therapy has significantly improved survival. Dinutuximab (also known as ch14.18 in early clinical trials or by its brand name “Unituxin”) is a monoclonal antibody designed to bind to neuroblastoma cells and stimulate the patient’s own immune system to target and kill the cancer. Dinutuximab is given in combination with medications (cytokines) that help to stimulate the immune system to generate these tumor-killing cells.

While there are a few different antibodies/immunotherapy regimens available throughout the world that are used to treat neuroblastoma, this chapter will focus on the history, use, and side effects associated with the first FDA-approved anti-GD2 antibody in the United States—dinutuximab.

It is important to remember that one patient’s individual experience with dinutuximab can be very different from others undergoing the same treatment. Questions about dinutuximab should be discussed with your child’s medical team since they are the primary source of guidance about every aspect of your child’s disease and treatment. We hope the following information will help you know what questions to ask your medical team and understand a little more about what to expect during this stage of high-risk neuroblastoma treatment.

### **How does dinutuximab work?**

Neuroblastoma can elude the immune system by using a number of tactics. Specifically, it is able to suppress the immune system’s ability to identify and destroy cancer cells. If the child’s body is to play a role in killing the neuroblastoma cells, the immune system needs some help in its ability to locate the cancerous cells. Helping the immune system find and kill the neuroblastoma cells is the purpose of the dinutuximab antibody therapy.

Dinutuximab is a type of “monoclonal antibody” (mAb). Specifically, dinutuximab is an “anti-GD2” antibody. This is because it works as a scavenger to find and bind to a substance on the surface of neuroblastoma cells called GD2. Once dinutuximab binds to GD2, it sends a signal to the body that tells the immune system an abnormal cell has been found and needs to be killed. This stimulates a response from the body’s own immune system to kill the neuroblastoma cell,<sup>1</sup> which is why dinutuximab treatment is referred to as “immunotherapy.”

Dinutuximab is given in combination with cytokines (like granulocyte macrophage colony-stimulating factor, GM-CSF, or interleukin-2, IL-2) because cytokines help boost the body’s immune response to better kill neuroblastoma cells.

## **How was dinutuximab developed and studied?**

Dinutuximab (also known as ch14.18 when it was being developed in early clinical trials prior to FDA approval) was developed over 20 years ago and has been studied rigorously by the Children's Oncology Group (COG) in thousands of patients at over 200 children's hospitals.

### **High-Risk Neuroblastoma Treatment**

In 2015, the FDA approved<sup>2</sup> dinutuximab as part of first-line therapy for children with high-risk neuroblastoma—the first approval of a therapy specifically for patients with the high-risk form of this disease. This approval was based on findings from a phase III clinical trial<sup>a</sup>, ANBL0032, conducted by the COG that focused on children with high-risk neuroblastoma who had responded to initial treatment with chemotherapy, surgery, stem-cell transplant and radiation. Patients were then randomly assigned to receive either an oral retinoid drug called isotretinoin, or isotretinoin plus dinutuximab, granulocyte-macrophage colony stimulating factor (GM-CSF), and interleukin-2 (IL-2). The results of this study,<sup>3</sup> which were published in 2010, showed that patients who received isotretinoin plus dinutuximab, GM-CSF and IL-2 had significantly better outcomes compared to those patients who received isotretinoin alone, including fewer patients who had the cancer come back or get worse (event-free survival) and fewer patients who had died from any cause (overall survival).

Results from an extended follow up period (median 9.97 years) for patients on this study were published in 2021, which again showed a significantly improved event-free survival and overall survival for patients who received dinutuximab immunotherapy compared with those treated with isotretinoin alone, albeit the magnitude of survival benefit was smaller due to late relapses.<sup>4</sup> Because the clinical trial was stopped early due to a significant benefit noted in the patient group receiving dinutuximab immunotherapy, the sample size was smaller than originally planned (which can make it more difficult to detect statistically significant differences between two groups), but clinically significant long-term differences in survival were still observed.

In 2019, results from clinical trials conducted by pediatric oncologists in Europe with dinutuximab beta, which is anticipated to be highly similar to dinutuximab, showed that adding IL-2 to dinutuximab beta did not help it work better, but instead increases the risk of side effects from treatment. Thus, IL-2 was removed from European protocols with dinutuximab-beta. Based on this information, the Children's Oncology Group decided to remove IL-2 from their clinical trials with dinutuximab. Patients continue to receive dinutuximab but will no longer receive IL-2 along with it, as recommended in the currently open upfront treatment trial ANBL1531 for patients who are newly diagnosed with neuroblastoma. Instead, all five dinutuximab-containing cycles of treatment use GM-CSF, which has a lower chance of side effects.

### **Relapse/Refractory Neuroblastoma Treatment**

Dinutuximab has also been studied in patients with relapse/refractory neuroblastoma. Results from ANBL1221, a phase II<sup>b</sup> clinical trial conducted by the COG, showed that the addition of dinutuximab and GM-CSF to chemotherapy (with irinotecan and temozolomide)

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<sup>a</sup> The purpose of a phase III clinical trial is to compare a new treatment regimen to the current standard of care treatment regimen. Researchers assess not only side effects but also determine which regimen works better.

<sup>b</sup> The purpose of a phase II clinical trial is to determine the effectiveness of a new treatment regimen and to further study its safety. Usually in a phase II clinical trial, everyone gets the same dose. But some phase II studies randomly assign people to different treatment groups.

had significant benefit for children with relapsed or refractory neuroblastoma. About half of the patients who received the dinutuximab plus chemotherapy regimen had a partial or complete decrease in tumor burden.<sup>5</sup> After these promising initial results, additional patients were enrolled and non-randomly assigned to receive chemotherapy (irinotecan and temozolomide) with dinutuximab and GM-CSF. Results of this expanded study<sup>6</sup> were published in 2020, showing again that children with relapsed or refractory disease benefited from this chemoimmunotherapy combination. In this larger study, nearly half (41.5%) of the patients who received the dinutuximab plus chemotherapy regimen had a partial or complete decrease in tumor burden, with about two-thirds of the patients (67.9%) living with neuroblastoma that did not get worse in the year after treatment (progression-free survival) and the majority of patients (84.9%) surviving the year after treatment (overall survival). This exciting data has supported the use of this chemoimmunotherapy regimen as standard treatment for children with relapsed or refractory neuroblastoma.

In efforts to continue to improve on the results from ANBL1221, the COG is studying the ANBL1221 regimen with or without the addition of DFMO in their ANBL1821 clinical trial. This trial is ongoing.

### **Novel Combinations & Approaches**

Researchers continue to investigate new approaches to increase antitumor efficacy and decrease the toxicities of anti-GD2-based immunotherapy, and identify biomarkers for patients most likely to benefit from immunotherapy.

Researchers are also trying to improve upon first-line treatment for children with high-risk neuroblastoma. A pilot study,<sup>c</sup> ANBL17P1, conducted by the COG, investigated whether immunotherapy with dinutuximab and GM-CSF could be added to cycles 3, 4, and 5 of induction chemotherapy for patients with newly diagnosed high-risk neuroblastoma. Primary questions included whether this would be safe and tolerable for patients, but secondary questions also included whether this additional immunotherapy made a difference. The data from this study is still being analyzed.

Dinutuximab is also being studied in a number of early phase clinical trials in combination with other novel agents. Some of these trials are being studied within the COG, while others are being studied within research groups like New Approaches to Neuroblastoma Therapy (NANT), Beat Childhood Cancer (BCC), and the Cancer Immunotherapy Trials Network (CITN) affiliated with the National Cancer Institute (NCI).

### **Dinutuximab Treatment Overview**

Dinutuximab is now given in many different protocols for both upfront treatment of high-risk neuroblastoma and relapsed/refractory neuroblastoma. Regardless of the protocol, dinutuximab is given daily for 4 days with each day's infusion going over 10 to 20 hours. For more detailed information on treatment regimens please refer to the "**Additional Information on Treatment Schedules**" section at the end of this chapter.

#### **Standard First-Line Therapy—"post-consolidation"**

Dinutuximab is part of the current standard of care for all high-risk patients on Children's Oncology Group (COG) protocols and is often referred to as the "antibody therapy" or "immunotherapy" phase of treatment. It is usually the last phase of treatment after patients complete induction chemotherapy, surgery, stem-cell transplant(s) and radiation. The

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<sup>c</sup> A pilot study is a small scale clinical trial that evaluates the feasibility and potential side effects of a new treatment regimen prior to expansion to a larger clinical trial.

immunotherapy phase lasts about 6 months and contains 5 cycles of dinutuximab. Each cycle lasts about one month.

A typical dinutuximab cycle in this regimen involves a combination of the following:

1. Antibody (dinutuximab)
2. Cytokine (GM-CSF)
3. Retinoid (isotretinoin)

For more information on treatment for high-risk neuroblastoma please contact your healthcare team.

### **Relapse/Refractory**

Dinutuximab is now also standardly used in combination with chemotherapy for children with relapsed or refractory neuroblastoma. This approach will be customized by your child's physician. Depending upon response, your child could get anywhere from 2 to 17 cycles of this regimen. Each cycle lasts about one month.

A typical dinutuximab cycle in this regimen involves a combination of the following:

1. Chemotherapy
2. Antibody (dinutuximab)
3. Cytokine (GM-CSF)

### **What to expect during a dinutuximab infusion?**

- To help prevent or lessen side effects associated with the dinutuximab infusions, your child will be given medications prior to each dose. These are often called “pre-medications.” These most often include:
  - A normal saline bolus to hydrate your child
  - Anti-histamines like diphenhydramine (Benadryl) to help prevent allergic reactions. They may be given every 4-6 hours. Your child may receive additional antihistamines if Benadryl is not sufficient to control reactions. These may include hydroxyzine, famotidine, cetirizine, or loratadine.
  - Acetaminophen/Tylenol is given to help prevent and control fevers. Tylenol may be given every 4-6 hours. If Tylenol is not adequately controlling fevers, ibuprofen may be given in special situations.
  - Pain medication is started prior to dinutuximab and will likely include a continuous pain medication infusion (i.e. morphine, hydromorphone, etc.) along with a PCA (patient-controlled analgesia) that will give an immediate dose of pain medicine when needed. Gabapentin may also be added to help with pain and is taken by mouth or through a feeding tube.
- Close monitoring during and after the infusion may include:
  - Vital signs are taken every 15 minutes for the first hour and then every hour until the dinutuximab infusion is complete
  - Oxygen saturation monitored with pulse oximetry
  - The healthcare team will monitor everything your child eats and drinks. They will also watch urine output closely and weigh the patient daily or twice a day.

- It is common to have labs drawn at least once a day. The most common labs are: complete blood counts (CBC), electrolyte panels (chemistry), and albumin levels.

### **Infusion Rates**

Each dose of dinutuximab is infused over 10- 20 hours per day.

The dinutuximab infusion may be paused at any time and the rate can be slowed if side effects occur (potential side effects are discussed below). It is not uncommon for the infusion to be slowed, especially in the first cycle or two. If severe side effects occur during an infusion, a “wait and see” approach may be taken the following day of the infusion by starting back up at the full rate and decreasing again if necessary. In particular, if the patient develops an infection during the administration of the antibody (i.e. positive blood culture), the infusion is required to be stopped for that round of treatment.

### **Central Lines and Ports During Dinutuximab**

A distinctive aspect of the dinutuximab treatment is that it requires several types of infusions, often simultaneously—the antibody itself, continuous infusion of pain medication, and any other medications used to help with side effects. For this reason, double-lumen central lines or double-sided ports are very helpful. However, circumstances can develop where even a double-lumen line is not sufficient for the number of medications needed. For example, while dinutuximab is being infused, it must have its own line into the body—it cannot be mixed with anything else. If the situation arises where there are not enough lines, a temporary line—peripheral intravenous catheter (PIV) or PICC line—may need to be placed.

It is recommended that you consult in advance with your medical team about what type of central line your child will have during this phase of therapy.

### **Likely Side Effects of Dinutuximab**

Most children experience some side effects during dinutuximab treatment. However most side effects subside soon after the infusion is complete. Some children will “perk up” within hours of the completion of the infusion whereas others may take a day or more to feel well again. Many side effects of dinutuximab are “minor”; however, the treatment does come with warnings about the potential for more serious side effects. As a result, immunotherapy is only administered in the inpatient setting. This allows for better monitoring of vital signs, patient supervision and access to specialized equipment and staff.

Despite the known toxicities of dinutuximab, long-term follow-up analyses show that all side effects appear to resolve with time.<sup>7</sup> To date, there are no known long-term side effects associated with dinutuximab.

For many children, side effects of dinutuximab are manageable and limited to the days of actual treatment. When the antibody is given alone there is little or no impact on blood counts and hence much lower numbers of neutropenia and opportunistic infections than is seen with some chemotherapy. Children are usually able to resume a normal schedule in between courses of dinutuximab therapy. Therefore, during this stage of treatment families may feel that they are beginning to see the light at the end of a long treatment tunnel.

Since antibody therapy has always been given in combination with other medications, side effect information about dinutuximab alone is not available. Side effects vary depending on the medications dinutuximab is given with, but common side effects experienced are discussed below.

**Pain:**

The most common side effect associated with dinutuximab is pain. The GD2 antigen found on neuroblastoma cells is also found on nerve cells and pain fibers. When dinutuximab binds to GD2 on nerve cells and pain fibers, it causes pain. Children most often describe this pain as centering in the abdomen, but it can also be described as tingling, burning, numbness, and general all-over body pain. Most children experience some degree of pain; however, the severity will vary greatly from patient to patient. Oncologists often point out that the presence or lack of pain is not indicative of how well the dinutuximab treatment is working.

Given that pain is expected, IV pain medications (e.g., morphine, hydromorphone, fentanyl, etc.) will run continuously while dinutuximab is being infused. Additional boluses may be required to address more severe or breakthrough pain. If the pain is not sufficiently controlled by traditional opiate drugs, it may be necessary to consider other options. If there is a “pain service” or “pain team” in your hospital, their expertise can help provide other options for your child. For example, since the pain may be “neuropathic” (i.e., caused by the stimulation of the nerve cells during the treatment), it may be possible to use other drugs such as ketamine or gabapentin in conjunction with the opioid drugs to better control the neuropathic pain.

Parents and patients often find it very helpful to discuss the options for pain control with their medical team before the treatment starts. You should discuss how pain has been managed earlier in your child’s treatment course, for example during autologous stem cell transplant, and which drugs worked well for your child. You may also want to talk with the medical team in advance about how the pain medications will be tapered off once the dinutuximab infusion is complete, so that there is no confusion. In many cases, the IV pain medications are kept running for at least 2 hours after the completion of the dinutuximab infusion daily.

As a general rule, it is necessary to address the pain quickly to get it under control as soon as possible. The longer any pain is allowed to build, the harder it may be to get it under control. With each dinutuximab infusion, you will get a better handle on how to help your child deal with the pain, the right times to give a specific pain medication bolus, and whether the dosing of the pain medications needs to be changed in any way. Some children experience the first wave of pain approximately 2 hours into the antibody infusion. Administering a bolus of pain medication at the point right before the child generally feels the first peak of pain may be a helpful measure.

While the use of opioids for pain control have shown to be safe and effective in this regimen, pain medications can carry their own set of side effects (for example, sedation and constipation). Talk to your team about what side effects to expect based on the pain regimen they use for your child. If you notice your child’s pain is not well-controlled discuss this with your medical team.

**Infusion Reactions:**

Because the immune system is activated during this treatment it can sometimes have an exaggerated response to the dinutuximab infusion. Symptoms of an infusion reaction may include rashes, hives, coughing, or wheezing. Infusion reactions can vary from minor to severe or may not appear at all. These reactions are typically managed with antihistamines such as Benadryl (diphenhydramine) and others like hydroxyzine or famotidine may be added if Benadryl alone does not control the reaction. During the dinutuximab infusion, antihistamines may be given around the clock to help manage infusion reactions.

It is important to let the medical team know if you notice any redness on your child's skin, the presence of hives (red or pink raised bumps on the skin), or if your child begins to cough while the dinutuximab is infusing. Infusion reactions can occur quickly and may escalate in severity during the course of the dinutuximab infusion in some children. If these develop, the medical team will stop the dinutuximab infusion and give medications to counteract the infusion reaction.

**Low Blood Pressure:**

Before the dinutuximab infusion begins, your child's "normal" blood pressure will be measured and used as a baseline during the infusion. Along with other vital signs, blood pressure will be checked frequently throughout the infusion. Your child will be given intravenous fluids before the infusion to help prevent low blood pressure. If your child's blood pressure reaches a reading that is too low (hypotension), the dinutuximab infusion may be paused or slowed down. Sometimes slowing or stopping the dinutuximab infusion is all that is needed. If stopping the dinutuximab does not improve the low blood pressure, an intravenous fluid bolus (saline) may be given. In rare situations where the blood pressure does not improve after the dinutuximab is stopped and/or a fluid bolus is given, medications to increase the blood pressure may be given (e.g., dopamine, norepinephrine etc.).

**Fluid Retention:**

Another common side effect of dinutuximab therapy is fluid retention from a process called capillary leak. When the immune system is activated and there are high levels of cytokines circulating in the body, blood vessels are dilated and can leak fluid into surrounding tissues causing fluid retention. Some children do not experience this, whereas some may experience it more frequently. Capillary leak and fluid retention happen more often when dinutuximab is given with the cytokine interleukin-2 (IL-2). This is one of the reasons IL-2 is not used as frequently anymore.

Throughout the treatment, the medical team will monitor your child's "ins and outs" to calculate fluid balances and make sure the child is not retaining fluid. Your child will also be weighed at least once a day. If your child is retaining fluid their weight will increase. If it appears that your child needs help removing the excess fluid from their system, medications such as albumin, packed red blood cells and/or furosemide (Lasix) may be ordered. Managing of fluid balances during the antibody infusion is a delicate balance that your medical team will address carefully.

If you notice your child develops puffiness in their face, hands, feet, or appears to be generally swollen, you should let your medical team know.

**Fever:**

During dinutuximab, many children may develop a fever. Fevers are a common side effect of immunotherapy and can be a sign that the immune system is activated. Children are often given acetaminophen (Tylenol) as a pre-medication before the dinutuximab infusion starts, but it is not uncommon for your child to develop a fever even after Tylenol has been given.

Along with other vital signs, temperature will be checked frequently during the infusion. The onset of a fever typically necessitates blood cultures and the start of antibiotics, which means more medications being given through the lines. If this occurs, discuss the options for antibiotics with your medical team.



**Visual Changes:**

Some children reported changes to their vision during the initial study of dinutuximab. This was rare, but in some patients these changes did not resolve. As a result, your medical team will monitor your child's eyes and vision closely during the infusion. If you notice your child develops blurred vision, sensitivity to light, or changes to their pupils let your medical team know immediately. They will examine your child and may pause the dinutuximab infusion until the symptoms resolve.

**Summary**

Dinutuximab was developed through years of rigorous study by the National Cancer Institute (NCI) and the Children' Oncology Group (COG) starting over 20 years ago. It has been safely given to over 2,500 children at over 200 children's hospitals.

The addition of dinutuximab antibody therapy in high-risk neuroblastoma has had a positive impact on survival. Long-term data shows that patients who receive dinutuximab after induction chemotherapy, surgery, autologous stem cell transplant(s), and radiation have fewer relapses than those that do not receive dinutuximab.

However, dinutuximab antibody therapy is not without side effects, but most families find that these side effects can be easily managed by their medical team. One patient's individual experience with dinutuximab may be very different from others undergoing the same treatment so it is important trust the expertise of your medical team in managing the individual needs of your child.

For more information on antibody therapy and dinutuximab please contact your healthcare team.

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with any comments*

**Appendix:****Additional Information on Dinutuximab Treatment Schedules****Standard Post-Consolidation Therapy (per ANBL1531):**

The chart below shows the days on which each medication is given.

Treatment schedule for Cycles 1-5:

Day	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14-24
GM-CSF		x	x	x	x	x	x	x	x	x	x	x	x	x	
Dinutuximab					x	x	x	x							
Isotretinoin												x	x	x	x

Course 6 is contains isotretinoin alone.

**Relapse & Refractory Therapy (per ANBL1221):**

The chart below shows the days on which each medication is given.

Treatment schedule for Cycles 1-17:

Day	1	2	3	4	5	6- 12
Temozolomide	x	x	x	x	x	
Irinotecan	x	x	x	x	x	
Dinutuximab		x	x	x	x	
GM-CSF						x

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