

Management guidelines for dermatologic adverse events (dAEs)

A healthcare provider's guide to help prevent, identify, and manage dAEs for patients using Optune Gio™ to help maximize time on treatment

Inform your patients to contact you as soon as they experience itching or redness



Scott is an Optune user and patient ambassador. Patient images reflect the health status of the patients at the time the photo was taken.

This brochure does not represent medical advice, but guidance based on clinical trial results and real-world clinical experience. Novocure® cannot give medical advice.

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OPTUNE
GIO™

Help prevent dAEs to maximize time on treatment

The most common adverse event associated with Optune Gio™ in clinical trials was skin irritation beneath the arrays. For this reason, it is important to monitor not only the patient's clinical status but also their scalp health. Early prophylactic interventions may decrease the risk and severity of dermatologic AEs.¹

Prophylactic tips for skin AE management ¹	Recommendations for patients and caregivers ¹
<p>Shave and prepare the scalp to maximize the skin's contact with arrays, and minimize erosions and other factors increasing the risk of infection</p>	<ul style="list-style-type: none">• Always wash your hands prior to array application• Shave the scalp completely every time arrays are changed, using gentle but firm circular motions• Use a clean, electric razor to avoid cuts• Apply mineral (baby) oil before shaving to cleanse the skin and help remove bacteria and scale
<p>Remove natural oils and any moisture (sweat) from the scalp before array application</p>	<ul style="list-style-type: none">• Wash the scalp with mild, fragrance-free shampoo (eg, baby shampoo) or dandruff shampoo• Wipe the scalp with a piece of gauze or a cotton ball soaked in first aid isopropyl alcohol (70%), unless there are signs of skin irritation• Before placing arrays, ensure the scalp is dry

Please see the Optune Gio™ Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions at [OptuneGio.com/IFU](https://www.OptuneGio.com/IFU)

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Additional prophylactic steps that may help to reduce the risk of dAEs

Prophylactic tips for skin AE management ¹	Recommendations for patients and caregivers ¹
<p>Careful application and removal of arrays is important to minimize the risk of skin irritation</p>	<ul style="list-style-type: none">• Change arrays at least every 3–4 days, or more frequently if they become wet or loosen• Apply mineral (baby) oil to the scalp to slowly and gently remove arrays. Do not pull the skin or forcefully rub the scalp to remove adhesive, this can lead to skin breakdown and irritation• Based on patient experience, arrays may also be removed in a hot shower by rubbing in a body wash containing coconut oil, causing the arrays to slide off the scalp• Monitor the skin and scalp for signs of irritation with every array change, and notify your healthcare provider if there are signs of irritation (taking a picture of the affected area is advised)
<p>Regularly reposition arrays to minimize direct pressure on the scalp and ensure avoidance of surgical scar lines</p>	<ul style="list-style-type: none">• At each array change, shift array placement by 0.75 inches, ensuring that pairs of arrays are moved together• Move arrays back to original position at the next change• Avoid placing ceramic discs directly over scars or surgical screws

Recommend breathable headwear to avoid overheating.¹

Visit <https://www.optunegio.com/starting-optune/getting-outdoors> for a list of head coverings

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Identifying key risk factors

Key risk factors associated with dAEs¹:

- ✓ Prior craniotomies, especially those that necessitated scalp reconstruction
- ✓ Placement of arrays (ie, ceramic discs) overlying scars or craniotomy hardware
- ✓ Concurrent treatment with high doses of systemic corticosteroids
- ✓ Treatment with oral antibiotics
- ✓ Concurrent administration of chemotherapy or targeted therapies
- ✓ Previous skin exposure to ultraviolet or ionizing radiation
- ✓ Pre-existing skin conditions or a history of contact dermatitis (eg, from tape adhesive or hydrogel)
- ✓ History of hyperhidrosis (excessive sweating)
- ✓ Persistent alopecia

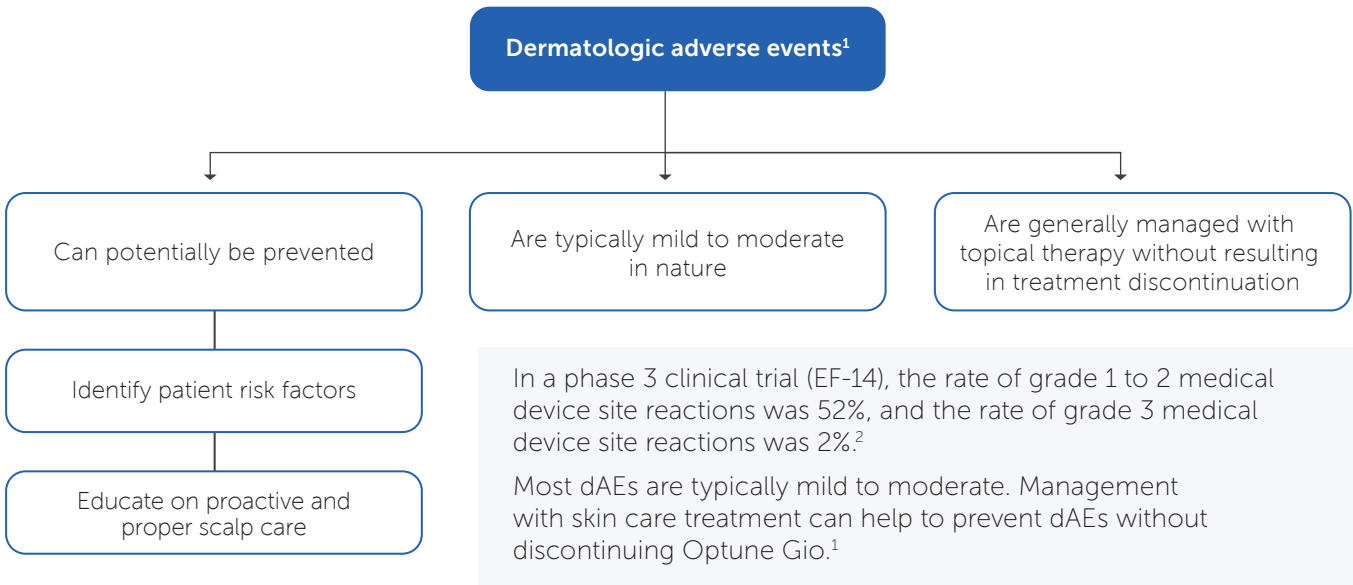
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Identify the types of dAEs patients may experience

Identification of patient risk factors, proper and timely array changes, and patient and caregiver education are all important for reducing the risk of developing skin irritation while on Optune Gio™.¹






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Causes and management of common dAEs

Treatment options for dAEs are dependent upon the type and severity of the dAE. If condition does not improve after intervention, consider dermatology consult.¹




Adverse Events	Description	Potential Cause(s)	Suggested Interventions
Hyperhidrosis¹ 	Excessive sweating of the scalp	<ul style="list-style-type: none"> • Genetic predisposition • Hot/humid climate • Intense activity • Medications 	<ul style="list-style-type: none"> • Aluminum chloride antiperspirant or topical glycopyrrolate at every array exchange • Avoid using ointments and medications that may cause sweating • Consider referral to a dermatologist for botulinum toxin injections
Pruritus¹ 	Dry skin (xerosis), itchy skin (pruritus), or flaky skin (dandruff)	<ul style="list-style-type: none"> • Genetic predisposition • Cold/dry climate • Loss of water/oil • Medications • May be related to contact dermatitis 	<ul style="list-style-type: none"> • Fragrance-free or anti-dandruff shampoo • Although part of the standard array change protocol, limit skin contact with alcohol-based products • Topical corticosteroids may be prescribed if inflammation is present (eg, betamethasone, clobetasol, fluocinonide) • Identify cause and, if possible, reduce or eliminate
Contact dermatitis¹ 	Contact Localized inflammation of the skin. Symptoms include skin rash that may resemble a burn or red bumps that form moist, weeping blisters	<ul style="list-style-type: none"> • Allergy to specific exogenous allergens, such as adhesive tape and/or hydrogel, that come into contact with the skin causing an inflammatory reaction 	<ul style="list-style-type: none"> • Immediate removal of the irritant/allergen • Array removal from irritation/allergen site • Topical corticosteroids, such as betamethasone, clobetasol, or fluocinonide • Apply a barrier film • Consider trimming adhesive or Surgilast® if reaction exists to tape or adhesive • If blistering develops, apply a cold, moist compress 3 times a day for 20 minutes • Consider systemic corticosteroids or treatment breaks if condition continues
	Irritant Localized dermatitis restricted to the area of the irritant. Symptoms include skin redness, mild edema, scaling, itchy or painful rash	<ul style="list-style-type: none"> • Nonspecific inflammation caused by direct cellular damage upon contact with an inherently harmful substance to cells, such as chemical irritation from hydrogel, moisture, and/or alcohol 	

Advise patients to avoid putting ceramic discs or adhesive tape over areas affected by a dAE when placing or exchanging arrays

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Causes and management of common dAEs (cont'd)

Adverse Events	Description	Potential Cause(s)	Suggested Interventions
Skin erosions¹ 	Moist, circumscribed, depressed, secondary lesions that involve the epidermis, but do not extend into the dermal layer	<ul style="list-style-type: none"> • Mechanical trauma from shaving and/or array application or removal • May develop from inflammation or maceration due to sweat, rupture of vesicles, bullae from infection, or epidermal necrosis 	<ul style="list-style-type: none"> • Array removal from site of erosion or ulcer. May consider replacement to avoid hardware exposure • Wound dressing with gauzes, hydrogels, or hydrocolloids • Assess wound and treat with topical antibiotics, such as clindamycin or gentamicin • May consider wound culture • Keep clear of excess discharge and dead skin. Severe cases may require surgical debridement • Return to clinic in 2 weeks. If condition continues, consider an oral antibiotic or treatment break
Skin ulcers¹ 	Secondary lesions involving the epidermal and dermal layers, which may result in scarring	<ul style="list-style-type: none"> • Ischemic injury and/or decreased perfusion produced by array pressure (especially in areas overlying scars, hardware, and prior radiation exposure) 	<ul style="list-style-type: none"> • Assess wound and treat with topical antibiotic, such as clindamycin or gentamicin • Warm compresses with saltwater or Burow's solution (5% aluminum subacetate) • Take wound culture and potentially refer to dermatologist • Return to clinic in 2 weeks. If condition continues, consider an oral antibiotic or treatment break
Dermatitis and infections¹ 	Inflammation of skin or hair follicle. Presentation includes pus, itching, or burning	<ul style="list-style-type: none"> • Secondary bacterial infection • If skin is affected by pathogenic bacteria, infection with or without pustules may occur 	<ul style="list-style-type: none"> • Assess wound and treat with topical antibiotic, such as clindamycin or gentamicin • Warm compresses with saltwater or Burow's solution (5% aluminum subacetate) • Take wound culture and potentially refer to dermatologist • Return to clinic in 2 weeks. If condition continues, consider an oral antibiotic or treatment break

Skin irritations associated with treatment with Optune Gio™ can usually be managed with proper skin care and the use of medications, such as topical corticosteroids and antibiotics, without discontinuing therapy¹

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| Instructions for application of topical therapy

Manually update the application directions on the prescription, especially the information in bold below

Patient instructions on how to properly apply topical medications:

- ✓ Remove arrays and clean scalp¹

- ✓ Apply topical agent (eg, steroid or antibiotic) to affected area(s)¹
 - Have patients only apply topical agents when they exchange arrays at least 2 times a week (every 4 days at most)^{1,3}
 - A thin layer should be applied to the dry scalp¹
 - Allow agent to dry¹

- ✓ Clean scalp with medical (70%) alcohol¹

- ✓ Apply new arrays to a dry scalp, ensuring that arrays are shifted “back and forth” approximately 0.75 inches at each exchange and are not placed over screws or plates¹

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Communication with the patient is key in helping to prevent and manage skin irritation



Gill is an Optune Gio™ user.

Please refer to the patient brochure, entitled *A guide to scalp care and proper array placement* (available in both English and Spanish), as an educational tool to use with your patients and their caregivers.

Contact a Novocure representative or go to OptuneGio.com for additional resources, including available styles for head coverings.

Note that neither a Device Support Specialist (DSS) nor a Care Coordinator (CC) at MyNovocure™ can manage skin irritation.

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Optune Gio™ Indications for Use and Important Safety Information

Indications For Use

Optune Gio™ is intended as a treatment for adult patients (22 years of age or older) with histologically confirmed glioblastoma multiforme (GBM).

Optune Gio with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery, and completion of radiation therapy together with concomitant standard of care chemotherapy.

Important Safety Information

Contraindications

Do not use Optune Gio in patients with an active implanted medical device, a skull defect (such as, missing bone with no replacement), or bullet fragments. Use of Optune Gio together with implanted electronic devices has not been tested and may theoretically lead to malfunctioning of the implanted device. Use of Optune Gio together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render Optune Gio ineffective.

Do not use Optune Gio in patients that are known to be sensitive to conductive hydrogels. In this case, skin contact with the gel used with Optune Gio may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions such as shock and respiratory failure.

Please see additional Important Safety Information on the next page.

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Optune Gio™ Indications for Use and Important Safety Information (cont'd)

Warnings and Precautions

The most common ($\geq 10\%$) adverse events involving Optune Gio in combination with temozolomide were thrombocytopenia, nausea, constipation, vomiting, fatigue, medical device site reaction, headache, convulsions, and depression.

If the patient has an underlying serious skin condition on the scalp (e.g. ulcers, open wound, broken skin) evaluate whether this may prevent or temporarily interfere with Optune Gio treatment.

Use of Optune Gio in patients with an inactive implanted medical device in the brain has not been studied for safety and effectiveness, and use of Optune Gio in these patients could lead to tissue damage or lower the chance of Optune Gio being effective.

Do not prescribe Optune Gio for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of Optune Gio in these populations have not been established.

Optune Gio can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure (the device manufacturer).

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References: **1.** Lacouture ME, Anadkat MJ, Ballo MT, et al. Prevention and management of dermatologic adverse events associated with Tumor Treating Fields in patients with glioblastoma. *Front Oncol.* 2020;10:1045. doi:10.3389/fonc.2020.01045. **2.** Stupp R, Taillibert S, Kanner A, et al. Effect of Tumor-Treating Fields plus maintenance temozolomide vs maintenance temozolomide alone on survival in patients with glioblastoma: a randomized clinical trial. *JAMA.* 2017;318(23):2306-2316. **3.** Optune Gio. Instructions For Use. Novocure; 2023.



Additional support and resources for your patient



The Buddy Program—Connects patients, and/or their caregivers, who have recently started or are considering treatment with Optune Gio™ with an ambassador. The ambassador is a patient or caregiver who has experience with Optune Gio and can share how he or she has learned to incorporate Optune Gio into his or her daily life. Call toll free at 1-844-247-1636 for the Buddy Program



The MyNovocure™ brochure—Provides detailed information on the 24/7 support patients and caregivers can expect with Optune Gio at every step of the way. Call toll free at 1-855-281-9301



OptuneGio.com/hcp—This online resource gives patients a wealth of information about Optune Gio, including where to find a certified treatment center. Here they can also view a range of videos and download resources



Optune Gio Facebook page—The Optune Gio US Facebook page provides information such as useful tips, answers to frequently asked questions, and information on upcoming events in the glioblastoma (GBM) community



Optune Gio YouTube Channel—Helpful videos present Optune Gio users and their doctors as they discuss GBM, Optune Gio, how it is applied and used, and how it allows for usual daily activities

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