

## CONSENT FOR PHOTODYNAMIC THERAPY (PDT)

**Please plan your PDT treatment for a time when you will avoid sunlight, even through windows, and bright indoor light, for the day of treatment and the two days that follow, to minimize excessive reactions and side effects to the PDT treatment. Avoid vacations if possible, especially to sunny climates, for two weeks after treatment, for the same reasons.**

Metvixia (5-MAL) and Levulan (ALA) are naturally occurring chemicals that, when applied to the skin, make the skin sensitive to light, including sunlight (direct or through windows) and bright indoor light of all types. THEREFORE YOU MUST AVOID SUN EXPOSURE AND BRIGHT INDOOR LIGHT FOR THE DAY OF TREATMENT AND THE TWO SUBSEQUENT DAYS. (Also, when you come to your appointment for PDT, please bring a hat with a wide brim and sunBLOCK that is Titanium Dioxide or Zinc Oxide based with an SPF of 30 or higher. You should also have protective clothing to wear after the treatment to cover other body areas that will be treated with PDT). When Metvixia or Levulan is applied to a skin area for a certain time, and that skin is exposed to light of a specific wavelength, in the medical office, the “sensitized” skin often develops a reaction. This reaction could include pain, “burning” or “stinging” while the light is applied to the skin in the office, or in the days after. Some element of redness, peeling, soreness, swelling, blistering, pustules, lightening or darkening of the skin, are also commonly seen after the office treatment, over the next few days to few weeks. For most people, the reaction and symptoms are mild/moderate and resolve within 8-12 days. Sometimes, either by design or without known cause, certain patients can have very prominent reactions to PDT, which may take 2-3 weeks to clear. This whole process described above is photodynamic therapy, (PDT).

PDT has been approved by the FDA to treat actinic keratoses (AKs) which are precancerous lesions of the skin from accumulated exposure to the sun or tanning beds, over our lifetime. Insurance companies generally cover PDT for AKs. AKs are important to treat and remove because they will, in some cases, turn into squamous cell skin cancer. In all cases, however, AKs indicate areas of the skin with significant damage from ultraviolet radiation (sun or tanning beds), and which are high risk areas to develop skin cancer(s). When the Metvixia or Levulan are applied to the skin, and allowed to "soak" into the skin, the chemical builds up in AK cells, basal cell skin cancer cells, and squamous cell skin cancer cells, to much higher concentrations, than normal cells attain. This makes these cells very sensitive to certain light. When cells full of Metvixia or Levulan are then exposed to these certain types of light, a reaction occurs that kills the cells. Generally speaking, the more cells that are killed with the PDT treatment, the more severe the reaction will be over the next several days after the treatment. Removing AKs will decrease your chance of getting skin cancer.

PDT has been shown to be very effective in treating some basal cell skin cancers, superficial squamous cell skin cancers, acne, rosacea, oil gland enlargement, and oily skin. PDT is also currently used, as it has been for many years, for “photorejuvenation”, meaning it can improve the appearance and feel of the skin from age/sun related symptoms of redness, brown patches, and roughness. Treatment of these conditions, while done widely, and often successfully, is considered “off label”, and not covered by insurance companies.

PDT Treatment Details

I understand that the area of my body to be treated with PDT will be cleansed, usually with rubbing alcohol or acetone. The Metvixia or Levulan will be applied to the area, and I will wait in the office for about 60-90 minutes, while the Metvixia or Levulan is absorbed by my skin. I will then be brought back to an exam room, where the Metvixia or Levulan will be wiped off. Protective eye shields will be placed over my eyes, and the Omnilux Red light or the Blu-U blue light will be shined on my skin to be treated, for about 10-30 minutes. When the Omnilux Red light or the Blu-U blue light is on, I understand the skin being treated may be somewhat uncomfortable, with “stinging” or “burning” the most common reported sensations. These types of feelings generally go away quickly when the light is turned off, and in most cases after a few minutes, even if the light is kept on. If these symptoms occur, the light could be turned off briefly, and then turned back on to complete the treatment, or I could refuse to continue the treatment. In either case, the PDT is completed at that point.

The Omnilux red light and Blu-U blue light are very bright when they are on. When they are turned on, you will be required to keep your eyes closed, and use protective eye shields for the entire time the light is on. When the face is being treated, the light will be especially bright. Please let us know if it is too uncomfortably bright.

Before treatment is performed, I need to tell the medical personnel if I: 1) am pregnant or breast feeding; 2) have a medical condition called “Porphyria”; 3) have a current or resolving case, or any history of cold sores. PDT should not be done if these conditions are present/active. If I have a history of cold sores, but not currently, I should get pretreatment with anti cold sore pills.

I do not have any of these conditions \_\_\_\_\_

I do have the following condition listed above \_\_\_\_\_

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Medical Staff Signature

\_\_\_\_\_  
Date

I understand I must tell the medical staff, before treatment, if I am allergic to peanuts or almonds or their oils, if

I am being treated with Metvixia cream. This is not a concern when using Levulan.

I am NOT allergic to peanuts, almonds, or their oils \_\_\_\_\_

Patient Initials

I AM allergic to peanuts, almonds, or their oils \_\_\_\_\_

Patient Initials

\_\_\_\_\_  
Medical Staff Initials

I understand that I also need to review with the medical staff, any medications I am taking, to see if any of them will make me even more sensitive to the PDT light treatment. Topical medicine such as Differin, RetinA, Tazorac, or any other creams that have these in them, should be stopped for a few days before PDT treatment.

I have reviewed my medications with the medical staff.

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Medical Staff Signature/Initial

I consent to the taking of photographs before, and after each treatment session, of PDT and the use of these photographs by Dr McGuiness’ office on their website, in office displays, advertising, or other purposes to promote the use of PDT.

\_\_\_\_\_  
patient initials

I consent to the taking of photographs before and after each treatment session of PDT, but do not allow the use of these photographs except for the following purposes:

\_\_\_\_\_  
patient initials

I do not wish to be photographed in any way concerning the PDT treatment.

\_\_\_\_\_  
Patient Initials

I understand that much of medicine is not an exact science, and there is no guarantee of the results I will have. I also realize that more than one treatment is almost always required to achieve the results I am seeking with PDT. I realize that often, the first treatment may not lead to obvious or significant symptoms or signs that the treatment “worked” (One reason, this might happen, is if you have treated the skin which is being treated with PDT, previously, with creams such as Carac, Efudex, Aldara, Zyclara, Solaraze, or had laser treatment or chemical peels, many of the “bad” cells, like AKs, may already be gone. Therefore, there may not be many “bad” cells left for the PDT to work on). I have been advised that this may be because “standard” settings are usually used for the first treatment, since there are some people, unknown before treatment, who have very significant reactions to the “standard” settings, and these people could be harmed if the “settings” were too strong. I understand that if my first treatment does not lead to any notable skin effects, or very mild skin effects, that the “settings” for subsequent PDT treatments will be increased. Ultimately, however, I understand that PDT may not be successful for me.

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Medical Staff Signature/Initial

\_\_\_\_\_  
Date

I understand that though I may have been “pre-certified” for PDT treatment to determine what my insurance company will cover for the PDT, that insurance companies will not truly guarantee whether PDT or any treatment will be covered, until an actual claim is submitted. It is rare that the insurance company would cover less than what the pre-certification indicated they would pay, but it could happen.

If it is determined after my treatment with PDT, and submission of the insurance claim, that my insurance company will not cover the PDT, that I will be responsible for up to \$350 per PDT treatment, regardless of what the results of the “pre-certification” may have found.

\_\_\_\_\_  
Patient Signature Date

\_\_\_\_\_  
Medical Staff Signature/Initials Date

I understand that there are other treatments that I could do instead of PDT, for AKs, including, but not limited to, topical creams/gels such as Carac, Efudex, Imiquimod, Aldara, Zyclara, Solaraze. Cryotherapy, laser treatment, chemical peels, microdermabrasion, and surgery, are also options. In fact Dr. McGuiness highly encourages the use of these treatments as well as PDT, to treat AKs and severely UV damaged skin, since rotating therapy among all these treatments is more successful, over time, of destroying more of the “bad” cells, and decreasing the chance of getting skin cancer. I also realize I could do no treatment at all.

\_\_\_\_\_  
Patient Signature Date

\_\_\_\_\_  
Medical Staff Signature/Initials Date

I agree that from the time my PDT treatment is completed until 72 hours later (3 days, including the treatment day), that I will avoid sunlight (even through windows), tanning beds, and bright indoor lights of any kind. During this time, I will wear a wide brimmed hat and Titanium Dioxide or Zinc Oxide based sunblock with SPF greater than or equal to 30, reapplied every 2-3 hours, and protective clothing, anytime sun light or bright indoor light is present, even through windows.

I have read the preceding information on PDT, and understand it. My questions have been answered to my satisfaction by the medical staff. I accept the potential risks and complications of the treatment. I agree that I will read if I have not already, the post PDT care and precaution instructions and follow them closely. I agree, with my signature below, to proceed with PDT treatment by the staff of Dr. Michael McGuiness, using Metvixia or Levulan

\_\_\_\_\_  
Patient Signature Date

\_\_\_\_\_  
Medical Staff Signature/Initials Date

CONSENT FOR PDT TREATMENT IF THE PATIENT HAS HAD RECENT PDT WITH DR MCGUINESS

If a patient has had a PDT treatment with Dr McGuiness office within the last six months, the patient may sign and date in the spaces provided below, to give informed consent for subsequent PDT treatments. The patient should review the four page PDT consent, and the one page PDT aftercare information sheet, prior to signing, and have all their questions answered satisfactorily. The current body location being treated by PDT should also be listed. By signing and dating in the space(s) below, the patient acknowledges that the preceding conditions have been met, and agrees to have PDT treatment with Dr McGuiness office.

current body area to be treated	treatment date	patient signature	staff initials
current body area to be treated	treatment date	patient signature	staff initials
current body area to be treated	treatment date	patient signature	staff initials
current body area to be treated	treatment date	patient signature	staff initials
current body area to be treated	treatment date	patient signature	staff initials
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