

## INFORMED CONSENT FOR KYBELLA® (DEOXYCHOLIC ACID) AESTHETIC INJECTABLE TREATMENT

**INSTRUCTIONS** - This is an informed-consent document that has been prepared to help inform you concerning using deoxycholic acid injection injections with Kybella®. The use of aesthetic injections with Kybella has its risks and alternative treatments.

**INTRODUCTION** - Kybella® is a cytolytic drug indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental (neck) fat in adults. The safe and effective use of Kybella® for the treatment of subcutaneous fat outside the submental region (neck) has not been established and is not recommended. Kybella® is injected into the fat under the chin (no more than 50 injections or 10mL under the skin). Kybella® injections will be given at least one month apart. Your healthcare provider will decide how many treatments and injections are needed. Any other cosmetic use is considered “off label.”

**ALTERNATIVE TREATMENTS** - There are alternative forms to Kybella® that are non-surgical and surgical. The non-surgical alternatives consist of topical neck products, weight loss, and neck homeopathic treatments. The surgical alternatives of Kybella® are a neck lift, neck liposuction, and several others. Risks and potential complications are associated with alternative forms of treatment.

**RISKS** - There are risks of using Kybella®. Every cosmetic procedure involves a certain amount of risk, and it is important that you understand the risks involved. An individual’s choice to undergo a cosmetic procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience complications, you should discuss each risk with your provider or affiliated medical personnel.

**IRRITATIONS** - Kybella® injections can cause tingling, swelling, itching, skin tightness, and headache. These side effects typically resolve without treatment and do not commonly result in patients discontinuing treatment.

**NERVE INJURY** - Although unlikely, Kybella® injections could cause nerve injury in the area of the jaw resulting in an uneven smile or facial muscle weakness. In the clinical trials these all resolved without treatment in an average of six weeks. Tell your provider if you develop signs of marginal mandibular nerve paresis (e.g., asymmetric smile, facial muscle weakness), difficulty swallowing, or if any existing symptom worsens.

**SWALLOWING** - Although unlikely, Kybella® injections can temporarily cause trouble with swallowing. Tell your provider if you have had a history of troubled swallowing before your treatment. If you experience any problems swallowing after your treatment notify your provider immediately.

**SKIN ULCERATION** - Although unlikely, Kybella® injections could cause superficial skin erosions.

**ALOPECIA** - Although unlikely, Kybella® injections could cause small patches of alopecia (hair loss) in the treatment area. The hair on a man’s beard can potentially experience patches of hair loss that may be permanent.

**BLEEDING** - It is possible to experience a bleeding episode during or after injections. Should post-procedure bleeding occur, it may require emergency treatment to drain accumulated blood (hematoma). Ask your provider before taking any aspirin or anti-inflammatory medications for ten days before your procedure, as this may contribute to a greater risk of bleeding.

**BLINDNESS** – Although extremely rare, aesthetic injectables can cause permanent blindness by blocking the blood supply to the eye. The highest risk areas are around the glabella (the skin between the eyebrows and above the nose), nasal region, nasolabial fold, and forehead. The most common

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symptoms are immediate vision loss and pain. Central nervous system complications related to the blindness can occur.

**INFECTION** - Kybella® should not be injected if there is a preexisting infection in the treatment area. In the rare event an infection occurred after treatment, additional treatment including antibiotics or an additional procedure may be necessary.

**BRUISING AND SWELLING**- Kybella® injections commonly cause swelling, bruising, pain, numbness, redness, and areas of hardness in the treatment area. You may have bruising within a week or more of having any injectables, so time your treatments with your schedule accordingly. Although wound healing after an injectable procedure is expected, you will want to keep ice on the treated area until it subsides. You may be asked to take a medication to reduce or prevent bruising such as Arnica Montana. Contact your provider if bruising lasts longer than a week or anytime if you are concerned.

**DAMAGE TO DEEPER STRUCTURES** - Deeper structures such as nerves, blood vessels, and muscles may be damaged during treatment with aesthetic injectables. The potential for this to occur varies according to where the treatment is being performed. Injury to deeper structures may be temporary or permanent.

**UNSATISFACTORY RESULT** - There is the possibility of an unsatisfactory result from aesthetic injectables. Aesthetic injectables may result in unacceptable visible deformities, loss of function, wound disruption, skin death, and loss of sensation. The procedure may result in unacceptable visible deformities or asymmetry in the treatment area. You may be disappointed with the results of Kybella®. The effectiveness of Kybella® may eventually subside but is not know when or if ever that will occur at this time. It is possible that Kybella® cannot be removed or corrected once inside your neck or body.

**ALLERGIC REACTIONS** - In rare cases, local allergies to injectables, lidocaine, or topical preparations have been reported. Systemic reactions, which are more serious, may result. Allergic reactions may require additional treatment. Lidocaine, a pain reliever used in most dentist offices, is an ingredient in many injectables. Tell your provider if you have an allergy to lidocaine or other allergies.

**MEDICATION REACTION** - Tell your provider if you are on, or were recently on, any medications as they may interfere with the ability of the aesthetic injectables to function. Even use of antibiotics and Aspirin should be brought to your provider's attention. It is not recommended that you undergo this treatment if you are on blood thinners for any reason including bleeding disorders.

**HERPES SIMPLEX VIRUS** - Tell your provider if you get cold sores, fever blisters, or have been diagnosed with the herpes simplex virus. For your comfort we will recommend that you call your physician before treatment so you can take preventive medication to avoid an outbreak. Aesthetic injectable fillers do not cause outbreaks, but can trigger a non-active outbreak.

**PREGNANCY** - Women should not have aesthetic injectables if they are pregnant or may become pregnant, or are breast feeding.

**PREVIOUS SURGERY** - Tell your provider about all past or planned surgeries and treatments of the face, neck, or chin as these could affect the effectiveness and safety of Kybella®

**ADDITIONAL TREATMENTS MAY BE NECESSARY** - In some situations, it may not be possible to achieve optimal results with a single aesthetic injectable treatment. Multiple sessions may be necessary. Should complications occur, additional injectables or other treatments may be necessary.

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**DISCLAIMER** – Informed consent documents are used to communicate information about the proposed injectable treatment along with disclosure of risks and alternative forms of treatments. The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

This informed consent should not be considered all inclusive in defining other methods of care and risks encountered. Your provider or affiliated medical personnel may provide you with additional or different information, which is based on all the facts in your particular case and the state of medical knowledge. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Kybella®. Other complications and risks can occur but are even more uncommon. The practice of medicine and aesthetic injectables is not an exact science. Although good results are expected, there cannot be any guarantee or warranty expressed or implied on the results that may be obtained.

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I hereby authorize Sheri Lynn Golden, MHS, PA-C, delegated staff, and such assistants as may be selected to perform the following procedure or treatment:

**Deoxycholic acid injection injections with Kybella® for improvement in the appearance of moderate to severe convexity or fullness associated with submental (neck) fat.**

I recognize that during the course of the injectable treatment, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician or affiliated medical personnel or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.

I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthetics involve risk and the possibility of complications, injury, and sometimes death.

I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.

For purposes of advancing medical education, I consent to the admittance of observers to my aesthetic injectables.

I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.

IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:

- A. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN.
- B. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT.
- C. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED.

I certify that I have read all pages of this document and give my consent for my injectable procedure.

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Patient Signature / Date

Witness Signature / Date

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Print Patient Name

Print Witness Name

I certify that I have explained the nature, purpose, benefits, risks, complications, and alternatives to the proposed procedure to the patient. I have answered all questions fully, and I believe that the patient fully understands what I have explained.

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Sheri Lynn Golden, MHS, PA-C / Date