



Botulinum Treatment Patient Consent

This consent form contains information about use of botulinum toxin (and any neurotoxin with an analogous mechanism to botulinum) for psychiatric treatment purposes including depression, anxiety, PTSD, OCD, or other conditions as discussed with your provider. **Please read this document in its entirety. Your signature on the last page indicates you have reviewed this information thoroughly.** This document was last updated 1/2021.

In order to begin treatment with us, we require you to read this entire agreement, ask any questions you have ahead of time, and seek outside advice or counsel about this agreement if needed.

You must agree to all of the terms here in order to proceed with treatment. By starting treatment with us, we assume that you do so agree, and have had all questions about your treatment answered to your satisfaction, and continue to agree to our terms as long as you are an active patient in treatment with us. You also agree that we may, at our sole discretion and at any time, change our terms of agreement for treating patients. This consent does not obligate us to treat you, and it is possible that we may determine at some point in the future that we are no longer able to treat you, and may need to cease treatment and/or discharge you from the clinic.

If you do not understand or agree to any of these terms (including from any language, educational, decisional capacity, or cognitive barriers), or have any other questions, please talk to your provider or call us prior to any treatment (303-801-1776 at the time of writing), and do NOT begin any treatment until you feel you have fully understood and agreed to this entire document.

OUTSIDE RESOURCES TO READ BEFORE STARTING TREATMENT:

IT IS CRITICALLY IMPORTANT THAT YOU READ AND UNDERSTAND THE [BOTULINUM \(onabotulinumtoxinA\) FDA INFORMATION FOR PATIENTS](#). (please call us if unable to access this link). If in the future we administer another form of toxin besides Botox, please advise us immediately to request information on the specific product, and you may also search the web for “FDA information for [name of product]” to read more.

This information presented above is for clients seeking treatment for cosmetic reasons, however, we inject Botox in a similar manner, and in the same sites, as used for cosmetic reasons, and so the information provided in this document is directly relevant for informing about possible risks and side effects from receiving this treatment. It is again imperative that you read this, and ask us any questions about it prior to starting treatment.

We administer Botox at sites on the face approved by the FDA, however, botox is **not** currently approved by the FDA for the treatment of psychiatric disorders. It is important to know and consider this when comparing to other possible treatments for your condition, including those that are FDA approved.

EFFICACY OF BOTOX IN TREATING PSYCHIATRIC DISORDERS:

Multiple clinical studies have been conducted over the past decade that suggest that botulinum toxin may be a safe, effective treatment for psychiatric disorders, such as major depression. It may also have efficacy for other disorders such as anxiety, PTSD, and borderline personality.

In 2020, a [Phase 2 Clinical Trial](#) of Botox for treatment of Major Depression was conducted. They found that “OnabotA 30 U, administered in a standardized injection pattern in a single session, had a consistent efficacy signal across multiple depression symptom scales for 12 or more weeks.” A [2016 review](#) of botulinum for the treatment of major depression identified 5 studies and 194 subjects. Their meta-analysis showed that response and remission rates for major depression were 8 and 5 times higher, respectively, among patients receiving botulinum toxin A compared with placebo. Of note, the glabella (between the eyebrows) appears to be the site with the most proven efficacy for depression as noted in this [2018 review](#). In our clinic, we typically target the glabella as the primary site, but will administer Botox at other approved sites in order to balance the effect on the whole face.

SAFETY:

We again ask that you read the [FDA information for patients](#) regarding risks of treatment with botulinum, as the side effects for cosmetic treatment are likely to be similar to those for treatment of psychiatric symptoms. The official patient information informs of risk of: dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, dry eyes; and drooping eyebrows.

In terms of safety specifically for those being treatment for psychiatric symptoms, a Phase 2 Trial published 2020, “OnabotA was generally well-tolerated: the only treatment-emergent adverse events reported in $\geq 5\%$ in either onabotA group, and more than matching placebo were headache, upper respiratory infection, and eyelid ptosis.”

A [2016 review](#) states that “a few subjects had minor side effects, which were similar between the groups receiving botulinum toxin and those receiving placebo.”

It is not currently known whether any toxin targeting muscles (such as botulinum) may induce or aggravate psychiatric disorders. Prior reviews of studies (eg the 2016 review referenced above) do not appear to indicate any emergent psychiatric concerns arising from this treatment. However, it is still important to familiarize with basic psychiatric safety and emergency planning, as found in our Patient Agreement.

EMERGENCY CARE

Please take time to re-read the Patient Agreement regarding safety and urgent care for psychiatric concerns. Treatment with botulinum should, in this respect, be considered as any other mental health treatment.

This practice is set up as outpatient treatment for patients and their families who are able to safely function outside of a more restrictive environment (such as a psychiatric hospital), and who can generally stay safe for at least a week or two at a time in between sessions or phone calls with Bloom. We **cannot** guarantee capacity for handling urgent or high needs cases that, for example, require multiple consultations per week, the ability to make same-day or same-week appointments, or that need 24/7 on call services.

If you are experiencing a medical (INCLUDING SIDE EFFECTS FROM BOTULINUM TREATMENT) or psychiatric emergency, or have a concern which requires immediate help, call 911, or proceed to the nearest emergency room if able to safely drive.

For psychiatric concerns, Denver Springs (720-643-4300) is a psychiatric hospital in the area that provides 24/7 crisis assessment, no appointment needed. If you are urgently wanting to talk to someone by phone, please call the Colorado Crisis Services at 844-493-8255 or text "TALK" to 38255.

Please do **NOT** wait for us to return your call to get help for an emergency.

We feel it is ESSENTIAL that you have an immediate, in-person exam for any concerns that cannot wait for routine call backs, so that your vital signs can be monitored, and so you can be examined by a trained professional, and then treated quickly if needed. This is much safer than attempting to manage by phone, including if you are not certain if the concern is an emergency.

We ask that all active clients of Bloom agree to immediately present for an in person exam for any urgent concerns, and NOT attempt to manage a crisis or emergency by phone (e.g. to not, as a first

step, call us and wait for a callback to manage it). Clients also should NEVER show up to our office outside of scheduled appointments for urgent help, as we are not currently equipped to provide this.

Certain side effects and symptoms can only be diagnosed properly by a medical or psychiatric exam, and some symptoms can mimic much more serious problems. Thus, presenting for an in-person exam at an urgent care/emergency facility helps remove uncertainty and ensure your safety. If you have any doubts about whether your concerns are serious, it is MUCH better to side with safety and get an in-person exam at an urgent care or emergency room. NEVER wait and wonder if something is serious! Get it checked out. If you do not understand or agree with this, it is **imperative** that you let us know immediately prior to any further services.

If you do experience a crisis/emergency, please immediately proceed for help, and call us after you are in a safe setting (e.g. the emergency room), and leave us a detailed voicemail at 303-801-1776. Please let us know what occurred and what hospital you are being treated by, so that we can follow up with you and request records from the facility if needed. Please review this patient agreement regarding expectations around call-back times from us as they also apply here.

ALTERNATIVE TREATMENTS INSTEAD OF BOTULINUM:

A number of treatment alternatives exist for treatment of psychiatric disorders, including many that are FDA approved. By engaging in treatment with botulinum, it is possible that this will displace another treatment that you might have done instead, and so it is important to know what the alternatives are.

Botulinum toxin is unique in how it affects your mood, and appears to be substantially different in its mechanism for alleviating mental health concerns compared to other conventional treatments. And again, other methods exist to treat depression which have different safety, efficacy, and logistics considerations, and should be considered carefully before starting.

Major Depression (MDD), PTSD and Bipolar Disorders are usually treated with oral medications such as antidepressant medications, anti-anxiety medications, and mood stabilizers. Many of these medications are FDA approved, and have been extensively studied, including their safety and efficacy. Many of them have been in use far longer than botulinum toxin, and so long term effects are better understood. These are often first-line treatments for patients with mental health concerns, and should be considered with your provider.

Supplements such as NAC, SAM-e, as well as healthy life interventions such as exercise are also known to help some patients with depression, anxiety, and other disorders. [Triple Chronotherapy](#) / sleep deprivation is another less-known method that can treat depression quickly, and is worth considering since it can work quickly, with strong effects. We are a proponent of triple chronotherapy and would be happy to talk more about this with you.

Other non-medication options also exist to treat conditions such as serious or treatment resistant depression, including Electroconvulsive therapy (ECT) and Transcranial Magnetic Stimulation (TMS). These treatments have also been extensively studied and are widely regarded as safe and effective, and have FDA indications for some conditions. Please ask us more about these if you are interested, or are unsure if these treatment modalities would be worth considering prior to botulinum toxin.

Psychotherapy is a proven treatment for all of the disorders discussed here, and can likely enhance the effectiveness of somatic treatments such as botulinum. We ask that all clients presenting for the concerns discussed here engage in psychotherapy, whether receiving botulinum or not. We also welcome collaboration with your therapist during your treatment process.

Again, botulinum is a novel psychiatric treatment—the primary studies have been with depression. It is not yet a mainstream treatment, though there are now many studies that demonstrate that it may be an effective treatment. Botulinum may not permanently relieve depression. If your depressive symptoms respond to Botulinum, you may still elect to be treated with medications and ongoing psychotherapy to try to reduce the possibility of relapse. Over time, you may also need additional Botulinum treatments or other therapies to maintain your remission.

CONTRAINDICATIONS TO BOTULINUM TREATMENT

Contraindications are similar to those seeking treatment for other disorders, including migraine or for cosmetic use. Please review the warnings and contraindications that can be found eg [HERE](#) and DO NOT proceed with treatment until you have fully reviewed and discussed any questions you may have.

Below we list SOME conditions to consider, but ask again that you review the entire list:

Pregnant women and nursing mothers are not eligible because of potential effects on the fetus, or nursing child. You should not seek treatment with botulinum if you are OR MAY BECOME pregnant or nurse during the time of treatment. Please notify us immediately if this is a concern.

Hypersensitivity or allergy to botulinum - botulinum should not be used by those who have shown hypersensitivity or an allergy to the drug.

Medical Conditions: Please let us know if you have muscle or nerve conditions such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome. Other medical conditions of concern include bleeding problems; have plans to have surgery; had surgery on your face; weakness of forehead muscles; trouble raising your eyebrows; drooping eyelids; any other abnormal facial change;

DRUG INTERACTIONS

While botulinum primary acts at local sites in the skin, it is possible that it could interact with medications you are taking. Please discuss any medications you are taking with your provider prior to starting treatment.

VOLUNTARY NATURE OF PARTICIPATION IN TREATMENT

Your decision to undertake Botulinum is completely voluntary. Before you make your decision about participating, you may ask and will be encouraged to ask any questions you may have about the process.

Your continued treatment with Bloom also does not necessarily depend on continued Botulinum unless there is a specific medical reason for this (eg if we believe that this is the only appropriate treatment for you, which is rare).

WITHDRAWAL FROM BOTULINUM TREATMENT IS ALWAYS YOUR OPTION!

Even after agreeing to undertake Botulinum treatment, you may decide to withdraw from treatment at any time.

INFORMED CONSENT ATTESTATION

Your execution of this agreement constitutes your acknowledgment that you have read and understand our expectations around urgent/emergency concerns, have had sufficient time to have any questions answered, and you agree to reach out for immediate, in-person help with emergency services for all urgent/emergency matters (as discussed above).

By signing this form, I agree that:

1. I have fully read and understood this entire informed consent form describing BOTULINUM treatment.
2. I have had the opportunity to raise questions and have received satisfactory answers.
3. I fully understand that BOTULINUM can result in a profound change in mental state and may result in unusual medical, psychological, and physiological effects.
4. I understand my 'typed name' below shows acceptance and validation of this Consent.
5. I understand the risks and benefits, and I freely give my consent to participate in BOTULINUM treatment as outlined in this form, and under the conditions indicated in it.
6. I understand that I may withdraw from BOTULINUM treatment at any time.

Printed Name: _____

Date: _____