Botox Cosmetic Issues

Anne M. Menke, R.N., Ph.D.
OMIC Risk Manager

DISCLAIMER: Recommendations presented here should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtain the same results. The ultimate judgment regarding the propriety of any specific procedure or treatment must be made by the ophthalmologist in light of the individual circumstances presented by the patient. This information is intended solely to provide risk management recommendations. It is not intended to constitute legal advice and should not be relied upon as a source for legal advice. If legal advice is desired or needed, an attorney should be consulted. This information is not intended to be a modification of the terms and conditions of your OMIC policy of insurance. Please refer to your OMIC policy for these terms and conditions.

INSTRUCTIONS: Review the consent form, modify it to fit your actual practice, and replace the OMIC letterhead with your own. Please offer the patient a copy of the entire form. The signed consent serves to verify that the surgeon has obtained informed consent from the patient; it can be copied and sent to the refractive surgery center or ambulatory surgery center as verification of consent.

Version 2/23/06

Cosmetic Botox injections are frequently administered in ophthalmology practices. These risk management recommendations are designed to promote patient safety and reduce the physician’s liability exposure.

• TRAINING
• Ophthalmologists should be trained in the cosmetic application of Botox.
  o Acceptable courses include “New Dimensions in Cosmetic Enhancements” sponsored by Professional Postgraduate Services, the AAO’s on-line course, and the course sponsored by Allergan.
  o In lieu of a course, physicians with prior experience using Botox for the treatment of disease may observe a trained cosmetic Botox user.

• SETTING
• Administer Botox injections in an appropriate medical setting.
  o Spas are generally not an appropriate setting since they do not have the medical personnel and equipment necessary to safely observe patients, deal with potential complications, and provide for the proper disposal of medical waste as required by OSHA but may be acceptable if these issues are addressed:
    ▪ the physician has a private room to take histories, provide consent, and perform the treatment
• the environment closely approximates the clinical setting of a medical office.
  o Injecting Botox in someone’s home, a hotel banquet room, or other public place presents additional liability problems and is discouraged.

• PATIENT ASSESSMENT
• Each patient should undergo a basic history and examination. This should include the intake of medical information, recording of allergies and medications, review of current medical problems pertinent to the use of Botox (such as pregnancy, neuromuscular disorders, old neurological diseases, etc.) and a description of the physical/anatomical findings pertinent to the cosmetic use of Botox.

• INFORMED CONSENT AND DOCUMENTATION
• Obtain and document the patient’s informed consent.
  o The consent should be updated annually or if the patient’s risk/benefit ratio changes.
• A sample informed consent form is included in this document. Physicians should review it and change it as necessary to reflect their practice.
• Generate and keep a medical chart for each Botox patient.

• ADVERTISING AND INCENTIVES
• Physicians should not provide incentives for patients to recruit other patients seeking Botox treatments.
• Advertisements must be reasonable and appropriate and must not imply guarantees or make misleading statements. See “Advertising Medical Services” and “Advertising Review Form” in the Risk Management Recommendations section of the OMIC website at www.omic.com for more information.

OMIC policyholders who have additional questions or concerns about Botox cosmetic are invited to call Anne M. Menke, R.N., Ph.D., OMIC Risk Manager at (800) 562-6642, extension 651.
Consent for Use of Botox Cosmetic

Indications and alternatives Botox is a brand name for botulinum toxin type A, a neurotoxin that blocks messages between muscles and the nerves that control them. The effects of Botox become apparent 2-5 days after injection and generally last for 4-6 months. The FDA has approved the use of Botox to treat facial dystonias (spasms), strabismus (crossed eyes), and to temporarily soften facial rhytids (wrinkles) between the eyebrows. While the FDA has not approved injections to improve the appearance of wrinkles in other areas of the face, physicians may perform these “off-label” procedures. There are alternatives to Botox, including no treatment, or medicines or surgery on my facial nerves and muscles.

Side effects and complications include but are not limited to:
1. Bruising
2. Undercorrection (not enough effect) or overcorrection (too much effect)
3. Facial asymmetry (one side looks different than the other)
4. Paralysis of a nearby muscle leading to: droopy eyelid, double vision, inability to close eye, difficulty whistling or drinking from a straw
5. Generalized weakness
6. Permanent loss of muscle tone with repeated injection
7. Flu-like syndrome or respiratory infection
8. Nausea or headache
9. Development of antibodies to Botox
10. Botox contains human-derived albumin and carries a theoretic risk of virus transmission. There have been no reports of disease transmission through Botox.

Contraindications You should not have Botox if: you are pregnant; nursing; allergic to albumin; have an infection, skin condition, or muscle weakness at the site of the injection; or have Eaton-Lambert syndrome, Lou Gehrig’s disease, or myasthenia gravis.

I understand the above, and have had the risks, benefits, and alternatives explained to me. No guarantees about results have been made. I give my informed consent for Botox injections today as well as future treatments as needed.

_______________________________ _________________________
Patient Signature     Date

Version 6/2/05