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Submitted via: policycomments@wpsic.com

Re: Public Comment for Proposed LCD – Botulinum Toxin Injections (DL39909)

Dear Drs. Schaening-Perez, Nachodsky, and Vlahakis,

The Society of Interventional Radiology (SIR) and the American College of Radiology (ACR) appreciate the opportunity to provide comments on the proposed Local Coverage Determination (LCD) related to Botulinum Toxin Injections, providing clarification regarding adherence to FDA label changes and Dosing Guideline requirements for serotypes. As medical specialty societies representing over 40,000 members, including U.S. physicians practicing in vascular and interventional radiology, the SIR and ACR are committed to advancing high-quality, image-guided, minimally invasive care that improves patient outcomes.

We would like to provide clinical input regarding the development of the new Local Coverage Determination (LCD) for Botulinum Toxin Injections. Specifically, we would like to address the omission of image-guided preoperative abdominal wall botulinum toxin injection to facilitate large ventral hernia repair as an adjunctive therapy in complex abdominal wall reconstruction.

Ventral hernias represent a protrusion of intra-abdominal contents through a defect or area of weakness in the anterior abdominal wall fascia and/or musculature. These hernias are commonly managed surgically by general surgeons due to associated pain, functional limitations, and negative impacts on quality of life, as well as to mitigate the risk of serious complications such as incarceration and strangulation. Despite appropriate surgical management, hernia repair is associated with recognized postoperative risks, including recurrence and small bowel obstruction related to postoperative adhesions. Such complications frequently necessitate additional interventions or hospitalizations, thereby increasing overall healthcare utilization and costs for payers.

For patients with large or complex ventral hernias, specialized centers increasingly employ preoperative adjunctive techniques designed to expand and relax the abdominal wall musculature prior to definitive reconstruction. Botulinum toxin (BTX) injection has emerged as a valuable adjunct to surgical repair by chemically inducing temporary muscle relaxation, thereby increasing abdominal wall compliance and facilitating tension-reduced closure. This approach is conceptually analogous to established techniques such as surgical component separation, progressive pneumoperitoneum, and the use of soft tissue expanders. [1,2] In this context, preprocedural BTX injection represents a necessary and effective alternative or complement to these traditional methods in appropriately selected patients.

A growing body of clinical evidence suggests that the use of botulinum toxin enhances abdominal wall compliance, facilitates tension-reduced fascial closure, and may contribute to improved operative efficiency and overall surgical outcomes in patients undergoing repair of large or complex ventral hernias.

Services interventions: Diagnostic and therapeutic

Ventral hernias are managed using open, laparoscopic, or robotic surgical techniques, typically incorporating prosthetic mesh, suture repair, or a combination of both. 4 Selection of the operative approach is guided by surgeon expertise, patient-specific anatomy, and hernia complexity. In the setting of large or complex abdominal wall defects, adjunctive strategies are often required to facilitate safe and durable repair.

The American Hernia Society recognizes botulinum toxin (BTX) injection as an adjunctive technique within the spectrum of component separation strategies for complex abdominal wall reconstruction. Guidance from the Society highlights several clinical considerations that may warrant component separation, including: (1) the need to achieve physiologic, tension-reduced fascial closure; (2) proximity of the hernia defect to challenging anatomic regions or bony prominences; and (3) optimization of the anatomic plane for prosthetic mesh reinforcement.5 Importantly, the Society acknowledges that the decision to pursue component separation is multifactorial and ultimately rests on the clinical judgment of the operating surgeon

Botulinum toxin was first introduced as an adjunct to abdominal wall reconstruction in 2009, demonstrating that temporary chemical denervation of the lateral abdominal wall musculature results in increased muscle compliance and functional lengthening, thereby facilitating abdominal wall closure.1 In contemporary practice, BTX is administered as a preoperative intervention, typically at doses ranging from 200 to 500 units divided among targeted abdominal wall muscle groups and delivered under image guidance approximately 2 to 6 weeks prior to definitive surgical repair 6-8. This approach serves as a minimally invasive, image-guided therapeutic adjunct that complements established surgical techniques in appropriately selected patients.

Scope and clinical indications

Incisional and ventral hernias represent a significant and growing clinical burden. Incisional hernias develop in approximately 15% of patients following surgical procedures that require incision of the abdominal wall. Risk factors for incisional hernia formation include prior abdominal surgery, underlying medical comorbidities, obesity, smoking, diabetes, and impaired connective tissue integrity. Given the high prevalence of these risk factors in the general population, a substantial number of patients are at risk for developing large or complex abdominal wall defects that require advanced reconstructive strategies.

In this context, botulinum toxin (BTX) injection has been increasingly utilized as a preoperative adjunct in the management of ventral and incisional hernias, particularly when traditional closure techniques are anticipated to be challenging. Identified clinical indications for BTX use include: 9,10

1. Large hernia defects, typically defined by a transverse defect width greater than 8–10 cm or a loss-of-domain ratio exceeding 20%
2. Anticipated difficulty achieving midline fascial closure based on surgeon assessment
3. Complex abdominal wall hernias requiring component separation strategies

4. Patients with a history of open abdomen or prior failed repairs
5. In appropriately selected patients, preoperative BTX injection serves as a targeted, minimally invasive adjunct designed to optimize abdominal wall compliance and facilitate successful reconstruction.

Rationale

A growing body of evidence supports that the clinical benefits of preoperative botulinum toxin (BTX) injection in abdominal wall reconstruction outweigh its associated risks. In a large meta-analysis by Timmer et al. involving 995 patients, preoperative BTX injection resulted in significant elongation of the lateral abdominal wall musculature—up to 6 cm in total—thereby increasing abdominal wall compliance and improving rates of primary fascial closure.1 Multiple additional studies, including those by Claessen et al., Sagar et al., and Dias et al., have similarly demonstrated increased muscle compliance, functional lengthening, and downgrading of hernia size following BTX injection, all of which contribute to higher rates of successful fascial closure.2,4,11

Further supporting these findings, Byers et al. reported outcomes from a retrospective cohort of 32 patients with complex incisional hernias, demonstrating successful fascial closure in 90.6% of patients following preoperative BTX injection. Notably, closure was achieved in 85.7% of patients with a history of prior hernia repair, with associated reductions in hernia size and recurrence rates among this high-risk population.8

Across the published literature, the documented benefits of preprocedural BTX injection include increased abdominal wall compliance and muscle lengthening, 1,2,4,8,11 downgrading of hernia defect size,2,8 improved rates of primary fascial closure,1,2,4,9,12-15 reduced hernia recurrence,8,12,13 decreased length of hospital stay, and avoidance or reduction in the need for more invasive component separation techniques (CSTs).12 Importantly, BTX produces a temporary and reversible effect, allowing sufficient time for postoperative healing while avoiding permanent neuromuscular alteration.

More invasive CSTs are associated with delayed primary closure and higher rates of wound-related complications. As such, preoperative administration of BTX offers a less invasive alternative or complement to surgical CSTs, particularly in patients with lower midline hernias or hernia widths less than 12 cm.12,16 Additionally, emerging evidence suggests that combining BTX injection with progressive pneumoperitoneum (PPP) can further increase intra-abdominal volume preoperatively, thereby enhancing the likelihood of achieving successful primary fascial closure in select patients.17,18

The American Hernia Society, along with multiple published studies, recognizes BTX injection as an established adjunct to component separation, often referred to as “chemical component separation”, reflecting its growing acceptance and utilization in contemporary hernia practice.[5] Across the studies cited, BTX injection has consistently demonstrated a favorable safety profile with minimal and transient side effects, 1,2,4-8,19-21 Reported adverse effects include temporary abdominal wall weakness affecting cough or sneeze, mild injection-site discomfort or bruising, back pain, and transient sensations of abdominal tightness or bloating.1 Importantly, these effects were self-limited and did not require medical intervention.1

Conclusion

The available evidence demonstrates that preprocedural botulinum toxin (BTX) injection for complex abdominal wall reconstruction is a safe and effective adjunct with a favorable side-effect profile when

compared with traditional surgical component separation techniques (CSTs). Established indications for BTX use include ventral or incisional hernias characterized by loss of domain exceeding 20% or a transverse defect width greater than 8–10 cm; however, the ultimate determination of medical necessity should remain at the discretion of the operating surgeon when a challenging fascial closure is anticipated.

Preoperative BTX administration plays a meaningful role in facilitating successful primary fascial closure, enhancing tissue compliance, reducing hernia defect size, and lowering recurrence rates. Collectively, these effects contribute to decreased operative complexity, shorter hospital length of stay, and reduced downstream healthcare utilization. From a patient-centered perspective, BTX use is associated with faster postoperative recovery, reduced pain and analgesic requirements, and improved functional outcomes following complex hernia repair.

Given its demonstrated clinical efficacy, safety, and potential to reduce overall healthcare costs, insurance coverage for preprocedural BTX injection is warranted. Coverage will support appropriate adoption of this guideline-aligned “chemical component separation” technique and advance shared goals of improving surgical outcomes, optimizing resource utilization, and delivering high-value care for patients undergoing complex abdominal wall reconstruction.

We appreciate the opportunity to provide meaningful feedback on the WPS proposed LCD for Botulinum Toxin Injections (DL39909). If you have any questions, please do not hesitate to contact SIR's Senior Manager of Health Policy and Economics, Ashley Maleki, at amaleki@sirweb.org or (703) 844-0378.

Sincerely,

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