

I am writing to appeal the above listed denial of services for Code J0585, Injection, onabotulinumtoxinA.

My understanding from speaking to your staff at the number provided, is that the denial of Code J0585 also implies the denial of all services such as Outpatient Hospitalization, Anesthesia and Physician Services, related to said injection. I did suggest during the phone call that I had some expectation of paying for the injectable agent itself if I could be covered for the associated services; but was advised by the telephone agent that this was not a possibility. Please advise if I have received incorrect information.

I see from the statement of “Your Appeal Rights”, that I may designate a representative to file an appeal at any level of the appeals process. I am at a disadvantage in appointing a Physician designee to do a peer-to-peer or other representation. This is because the Practitioner I see regularly for my complex pelvic pain condition is a Physician’s Assistant who works in an Osteopathic Clinic which does not offer guided injections or other such procedures. So, when my primary provider of care and myself agree to the wisdom of pursuing a particular course of treatment, I must be farmed out to a third party Physician who does the procedure but cannot be made fully familiar with the complexity of my medical history. I therefore designate MYSELF as my own representative throughout the appeals process. I am my own health care coordinator and the head of my health care team. I expect to be afforded every courtesy that would be afforded to a Physician Designee, including telephone access for peer-to-peer review. I do consider myself the peer of any Physician on your staff when it comes to understanding of complex pelvic pain syndromes. This is formal written notice that I am the primary contact and designee for this appeals process.

The secondary contact shall be Isaac Tunnell, PA-C, of Accelerated Rehab and Pain Center, 241 N. Buffalo Dr. Bldg 1, Las Vegas, NV89145 / phone (702) 876-2225 / fax (702) 876-9635. Mr. Tunnell is the primary pain Practitioner whom I see on a monthly basis, and will be able to provide a coherent representation of my condition and treatment goals. He has written a summary progress note which is attached (**Exhibit 1**).

While I have every confidence that Dr. Harb, the Physician that submitted Code J0585, is a competent Practitioner who can effectively carry out this procedure; my history with him is a single office visit. He and his staff should not be unduly burdened with this appeals process.

In this appeal I shall demonstrate the following:

1. That due to my history, BOTOX injection to the piriformis is an appropriate next step in my individual plan of care, regardless of generic regulation.

2. That symptoms such as mine do in fact, based on the anatomy, have potential to be caused by piriformis syndrome.
3. That your review of the literature on BOTOX treatment of piriformis syndrome, as described in Policy # DRUG.00006, is incomplete; and that sufficient evidence does in fact exist within the literature to fully justify the use of BOTOX injection as a treatment for piriformis syndrome.
4. That the language in your Policy # DRUG.00006 is contradictory, and does in fact itself include language supportive of a claim for BOTOX injection to treat piriformis syndrome.
5. That if denied for BOTOX injection based on my other diagnoses, I carry sufficient Neurogenic urinary diagnoses to be approved for BOTOX Injection.
6. That while the denial letter I received states that use of BOTOX for pelvic floor dyssynergia is considered investigational, there is no corresponding review of the literature to demonstrate this within your Policy # DRUG.00006; and that there is in fact supporting evidence that BOTOX injection has efficacy in the treatment of pelvic floor dyssynergia.

These 6 points are discussed in order below, with **Exhibit** numbers corresponding to attachments. Each paper is hand-labelled with the Exhibit number at the top of the first page.

2. Due to my history, BOTOX injection to the piriformis is an appropriate next step in my individual plan of care, regardless of generic regulation.

The first step in appropriate management of health care costs is to look at the cost - benefit analysis as it applies to the patient, not to a piece of paper. I will walk you through a brief history of my complex pelvic pain disorder, to enhance your understanding of why BOTOX injection to the piriformis is currently the most conservative and cost effective option.

My pelvic pain syndrome began with interstitial cystitis in 1985, diagnosed via cysto /hydro in 1987 (**Exhibit 2**). As treatments for this (bladder instills, urethral dilation, various meds) were not helpful but I was able to achieve a good quality of life with lifestyle changes alone, I did not seek medical care for this condition after 1988.

I gave birth to my second child in 2004 and shortly thereafter began to experience numbness and neuropathic itch, increasing and spreading gradually first to my toes and feet, then to my upper/frontal pubic region, and finally to the anal region. While I did seek care for these, due to my atypical symptoms of neuropathic itch (which is

indistinguishable from neuropathic pain on EMG but subjectively experienced as severe intractable itch), I sought care in the wrong places, with Dermatology, Allergy, and Nutrition. I did not learn that my symptoms might be neuropathic until I traveled to Mayo Clinic Dermatology in late 2008 and an EMG was suggested.

In 2009, I had an acute exacerbation of bladder symptoms, with severe Neurogenic bladder spasms that left me unable to function in many areas of daily living.

I saw moderate improvement of bladder symptoms with Pelvic Floor Physical Therapy but no relief of other neuropathic symptoms. My Physical Therapist was able to identify numerous manifestations of pelvic / sacroiliac joint dysfunction, including a 1.5 inch leg length discrepancy with much greater muscle development on the side of the longer (right) leg. I had much greater weight-bearing right than left, and severely hypertonic musculature throughout the pelvis as well as much of my body.

I am able to trace at least some of this asymmetry back to the time of origin of my interstitial cystitis, as persons who were in my life from that time forward did admit to having noted my compensatory posture (habitual standing with right hip pushed out), and had interpreted it as “attitude”, “sexiness”, etc. Because my symptoms of Interstitial cystitis began on a backpacking trip, my assumption is that I acquired at least some of my pelvic joint injuries at that time and hence have been developing secondary muscular damage for 25 years.

In the winter of 2009, after unsuccessful attempts to fully correct my pelvic asymmetry with hands-on work and core exercises, my Physical Therapist referred me to Jerry Hesch, MHS, PT, whose practice focuses solely on Manual correction of joint dysfunction. Mr. Hesch’s report is attached (**Exhibit 3**). The treatment received from Mr. Hesch greatly improved my bladder and moderately improved my neuropathic itch symptoms. I became able to resume many normal activities of daily living, with the caveat that I cannot work in most professions due to lifestyle restrictions, and I must remain on an objectionable amount of medication for neuropathy (currently gabapentin 2400 mg daily, nortriptyline 50mg daily, diazepam 15mg daily). My employment opportunities and quality of life are further compromised because I experience memory loss, trouble expressing myself verbally, and weight gain secondary to these medications.

Although I have experienced little subjective bladder distress ever since my underlying pelvic joint dysfunction was resolved, I still do have painless excess residual after a void, as demonstrated by urodynamic testing (**Exhibit 4**). This causes me to struggle with frequent bladder infections. As a result, I am regularly prescribed prophylactic antibiotic therapy by my Gynecologist. More recently, the necessity of frequent antibiotic use has led to a further struggle with vaginal yeast infections, a situation which my Gynecologist is attempting to address to prevent further erosion of my quality of life. I also continue to have stress incontinence.

My situation for the past 1.5 years has been one where I have been able to function in a low-demand, disability friendly part time work environment, take daily medication, and struggle to remain free of infection as noted above. I am restricted due to neuropathic

itch in what I can wear, and must be constantly vigilant to maintain bathroom access as my only relief from frequent episodes of “beakthrough itch” is the application of OTC topicals (capsaicin, menthol). I am not satisfied with this quality of life, because I experience daily, intractable discomfort, incidents of public humiliation, and am medicated to a degree that I cannot see continuing year after year for the remainder of my lifetime. So, I continue to seek further improvement or a cure.

I had pudendal nerve blocks without long term improvement, indicating that there is still an exacerbating factor, such as an entrapment, irritating the pudendal nerves.

In May of 2010, I had my pelvic area imaged via MR Neurography. The report is attached (**Exhibit 5**). The reported results include bilateral pudendal nerve inflammation, greater muscle development and spasm right vs. left, bipartite (split) piriformis muscles, and bilateral Tarlov cysts at S2. Dr. Aaron Filler, who examined me before ordering the MRN and wrote the report on the films, was most interested in the state of my piriformis muscles and recommended that these be injected, as he suspected this to be the source of pudendal nerve entrapment. He had found the piriformis to be tight, tender, foreshortened and spastic bilaterally on exam, right worse than left. He also noted neuropathies of the foot including areas of poor sensation and reduced ankle reflexes, in addition to my subjective report of neuropathic itch of the toes. He stated to me that he believed this to be due to entrapment of some elements of the sciatic nerve, in addition to pudendal, within the piriformis.

I was unable financially to pursue piriformis injections with Dr. Filler, as he charges above what is usual and customary and is an out of network provider. So, I went in-network and had steroid injections to the piriformis done bilaterally by Dr. Fishell. These not only did not release the piriformis muscle, but caused a mild transient increase in pudendal symptoms and a more severe and longer lasting episode of painful sciatica. The sciatica did abate after approximately one month, although I am now prone to returning sciatic pain with prolonged sitting. I still have no answer as to whether releasing the tightness of the piriformis muscles would help my neuropathy, as the piriformis muscles were never relaxed as was intended with the steroid injection. Meanwhile, I also recognize persons with S2 Tarlov cyst Disease tend to have a similar symptom complex to my own, including pudendal symptoms, interstitial cystitis, and residual urine. I am awaiting a phone consult with a Neurologist who specializes in Tarlov Cyst Disease, and expect to pursue a diagnostic S2 block followed by Tarlov cyst surgery, if indicated. I have also noted that the classic treatment for pudendal neuralgia following first - line interventions such as Physical Therapy and nerve blocks, is pudendal nerve decompression surgery.

These options carry a comparatively much greater expense and risk, than does a simple trial of BOTOX injection to the piriformis. I do not believe it is in the best interest of Anthem any more than it is in my own best interest, to pursue these avenues prior to ruling out the piriformis as the underlying cause, through BOTOX injection.

To summarize: My argument is that the least expensive, most conservative, avenue of treatment left open to me is BOTOX to the piriformis. Failure to cover this would

subject me to a more expensive, riskier course of treatment without first ruling out the cheapest and safest. If this appeal is denied, I require that you address specifically in writing, how it is of benefit to either Anthem or to myself the patient, to deny me the least expensive, least invasive option.

2. Symptoms such as mine do in fact, based on the anatomy, have potential to be caused by piriformis syndrome.

As stated prior, I do have some indication of sciatic entrapment including reduced sensation and neuropathic itch in the toes and feet, and intermittent sciatic pain in the legs. However my main intent is to provide references which will demonstrate that the pudendal nerve can become entrapped in piriformis muscle and / or become entrapped secondary to piriformis syndrome; and that pudendal neuralgia can occur secondary to piriformis syndrome.

I am providing abstracts only, and one even briefer bibliographical reference, to cited journal articles as I believe you are in a better position than myself to access the complete text.

The article I have found most frequently cited in more current articles as a support for pudendal neuralgia secondary to piriformis syndrome, is too old for me to access even the Abstract without undue expense. The citation is:

EW Retzlaff; AH Berry; AS Haight; PA Parente; HA Lichty; DM Turner; AA Yezbick; JS Lapcevic; and DJ Nowland, The Piriformis Muscle Syndrome, *J Am Osteopath Assoc*, June 1974; 73: 799.

Other references are attached:

Kocabiyik et al, *The Course an Branching Pattern of the Pudendal Nerve in the Fetus* (**Exhibit 6**)

Filler AG, *Diagnosis of Pudendal Nerve Entrapment Syndrome Subtypes: Imaging, Injections, and Minimal Access Surgery* (**Exhibit 7**)

I have also included a self published case study by Dr. AG Filler (**Exhibit 8**), which describes successful use of piriformis injection to combat symptoms of pudendal neuralgia.

I did not try to dig up reams of additional articles on the piriformis - pudendal connection as I believe it to be self evident from the anatomy. If my appeal is denied, please state explicitly in writing whether you accept or reject the concept that piriformis syndrome can result in pudendal neuralgia. If you reject this concept, I can work to build a more extensive case from the literature.

3. *Your review of the literature on BOTOX treatment of piriformis syndrome, as described in Policy # DRUG.00006, is incomplete; and sufficient evidence does in fact exist within the literature to fully justify the use of BOTOX injection as a treatment for piriformis syndrome.*

Your review of the literature regarding the emergent practice of treating piriformis syndrome with BOTOX injection is out of date, your most recent reference being from 2002. You cite 3 studies, for which I have also attached abstracts: Childers, 2002 (**Exhibit 9**), Fishman, 2002 (**Exhibit 10**), and Porta, 2000 (**Exhibit 11**).

You neglected to mention Fanucci, 2001 (**Exhibit 12**), Lang, 2004 (**Exhibit 13**), or Yoon, 2007 (**Exhibit 14**). I have also attached a retrospective article by Yaron River, MD (**Exhibit 15**)

There might be additional studies which I did not cite, but the end result is, peer review articles providing a review of the literature consistently disagree with your conclusion on the evidence for efficacy of BOTOX injection for piriformis syndrome. The following literature review articles are listed and abstracts attached, with brief quotes from each abstract printed below:

3. Rawicki, 2010 (**Exhibit 16**) “Class 1 evidence is available for the treatment of... piriformis syndrome, myofascial pain...neuropathic pain (with BoNT-A)”.
4. Guerineau, 2010 (**Exhibit 17**) “Botulinum injections have been shown to be effective in piriformis syndrome”.
5. Kirschner, 2009 (**Exhibit 18**) “Recently, the use of botulinum toxin (BTX) to treat PS (piriformis syndrome) has gained popularity. Its use is aimed at relieving sciatic nerve compression and inherent muscle pain from a tight piriformis. BTX is being used increasingly for myofascial pain syndromes, and some studies have demonstrated superior efficacy to corticosteroid injection”.
6. Jeynes, 2008 (**Exhibit 19**) “The weight of evidence is also in favor of BTX type A and type B in piriformis syndrome”.
7. De Seze, 2003 (**Exhibit 20**) “Three hundred and seventeen articles were collected and 12 clinical trials were retained. They are focused on 4 chronic diseases, neck pain, tennis elbow, piriformis syndrome and low back pain...Results of the 6 chronic neck pain studies are contradictory and emphasize the difficulty to display a satisfactory analgesia effect of BTXA in this indication. Results of the studies concerning other indications (tennis elbow, piriformis syndrome, and low back pain) seem to be more effective and clinically pertinent”.

As you can see, these abstracts have been listed in ascending order by year of publication, with the more positive affirmations of BOTOX injection for piriformis

syndrome appearing in the most recent reviews of the literature. The oldest article is from 2003 and the newest from 2010. I believe that this trumps your review, which does not reference any study published later than 2002.

4. The language in your Policy # DRUG.00006 is contradictory, and does in fact itself include language supportive of a claim for BOTOX injection to treat piriformis syndrome.

I quote directly from Policy # DRUG.00006:

“Spasticity and Dystonia

The use of botulinum toxin therapy is a well-established, safe and effective treatment for a variety of spasticity related disorders and abnormal muscle tone, including muscle over-activity or spasticity related to upper motor neuron (UMN) syndrome caused by cerebral palsy, multiple sclerosis, stroke, spinal cord injury, or neurodegenerative disease. Controlled clinical trials of botulinum toxin injections for focal muscle spasticity have demonstrated prolonged yet reversible clinical improvements in physical function and comfort, as well as improvement in prevention or treatment of musculoskeletal complications. These benefits have been achieved with few side effects.

Botulinum toxin treatment has been demonstrated to be a safe and effective method for decreasing the severity of abnormal head positioning and postures and pain associated with various dystonias such as cervical, spasmodic, and torsion dystonia. Although botulinum toxin therapy has not resulted in complete relief of symptoms for these conditions, clinical trials have demonstrated temporary but significant improvements in the degree of muscle contractility, flexibility, and pain. An added benefit of this treatment is the ability to target specific muscles in a dose-response relationship, allowing a precise amount of muscle weakness to be induced.”

Basically, you are saying here that BOTOX injection has been demonstrated to be a safe and effective treatment for muscle spasticity and dystonia in general, however then you go on to deny its use for a *specific* muscle. I believe this is done in bad faith, as you recognize the value of the treatment but deny it only because you can. Research on emergent treatments is introduced significantly later than is widespread use in clinical practice, because a researcher must take the initiative to set up and fund a study. For BOTOX you are insisting that such studies not only be set up and funded in large volume, but also that they be done in large volume with focus on each particular muscle in isolation. You know as well as I do, that BOTOX is capable of reducing muscle spasticity and dystonia in the piriformis; and your general statement about the efficacy of BOTOX injection for spasticity and dystonia, as quoted above, proves this to be so.

I would also like to state that while you indicate above that improvement is temporary, this is based on studies where the modality used has been BOTOX alone. I have every reason to expect that if my neurogenic symptoms do in fact prove to be related to piriformis syndrome, I will see permanent gains as the underlying joint dysfunction and gait abnormality have been corrected.

5. If denied for BOTOX injection based on my other diagnoses, I carry sufficient Neurogenic urinary diagnoses to be approved for BOTOX Injection.

Your Policy # DRUG.00006 is significantly friendlier to usage of BOTOX for neurogenic Urologic uses, than it is to usage for pelvic floor symptoms.

I would like to direct you again to my diagnosis of interstitial cystitis (**Exhibit 2**), and to my urodynamic testing papers (**Exhibit 4**) which list the diagnoses of interstitial cystitis, incomplete bladder emptying, incontinence-female stress, and urinary urgency.

While my bladder is much improved, I do still experience erosion of quality of life due to incomplete bladder emptying and stress incontinence. The interstitial cystitis is in long term remission however it still stands as a chronic and hence pertinent diagnosis. I am making my backup literature brief as it would seem from Policy # DRUG.00006 that you already do acknowledge the value of BOTOX for neurogenic urinary conditions; however I am attaching abstracts from two articles I think might be pertinent.

The first, Jasmin 1998, (**Exhibit 21**), is not very useful in abstract form; however if you acquire the article you will see that it develops an excellent animal model to build a case that interstitial cystitis can be of neurogenic origin secondary to muscle spasm.

The second, Sinha 2007, (**Exhibit 22**), is a literature review entitled “Applications of Botulinum Toxin in Urogynaecology”, which lists applications in “neurogenic and idiopathic detrusor over activity, detrusor sphincter dyssynergia (DSD), interstitial cystitis, and pelvic pain”.

You have so far stated that you have rejected me for BOTOX injection on the basis of my having piriformis muscle and pelvic pain. I hereby formally request that you do include in your evaluation of my case, all my Urologic diagnoses.

6. While the denial letter I received states that use of BOTOX for pelvic floor dyssynergia is considered investigational, there is no corresponding review of the literature to demonstrate this within your Policy # DRUG.00006; and that there is in fact supporting evidence that BOTOX injection has efficacy in the treatment of pelvic floor dyssynergia.

Especially in light of your general positive statements about use of BOTOX for spasticity and dystonias, I was surprised and disappointed to see that in Policy # DRUG.00006 there is no specific review of literature regarding the use of BOTOX injection in pelvic pain syndromes; it must have just been lumped in with “other”. And so once again a neglected and suffering population is further neglected and allowed to suffer. I am providing the following abstracts to aid you in creating a proper review of the use of BOTOX injection in the treatment of chronic pelvic pain:

8. Gottsch, 2010 (**Exhibit 23**)
9. Rognlid, 2010 (**Exhibit 24**)
10. Abbott, 2009 (**Exhibit 25**)
11. Jabbari, 2008 (**Exhibit 26**)
12. Abbott, 2006 (**Exhibit 27**)
13. Jarvis, 2004 (**Exhibit 28**)
14. Romito, 2004 (**Exhibit 29**)

I have also included an article which appeared in Internal Medicine News, 11/11/10, (**Exhibit 30**), Entitled “Botox Eases Pain of Pelvic Tension Myalgia”. This article covers a lecture given by Dr. Michael Hibner, a leader in the clinical treatment of pelvic pain, for the International Pelvic Pain Society Conference. Dr. Hibner is quoted as stating, “For pelvic floor tension myalgia, Botox is definitely beneficial... We do it quite often, almost on a daily basis”.

As I mentioned before, this demonstrates the disparity between what is being done for patients in the clinical setting, vs. the lag time before it makes its way into numerous Class 1 studies and Journal articles. You are denying a modality which is well accepted amongst the best clinicians, to be beneficial.

Thank you for your time. I do expect to appeal this up through any and all channels if necessary; so if you deny this appeal please do so in a detailed written statement directly addressing all the points made in this appeal.