

Affected Programs: BadgerCare Plus, Medicaid

To: Federally Qualified Health Centers, Hospital Providers, Nurse Practitioners, Pharmacies, Physician Assistants, Physician Clinics, Physicians, Rural Health Clinics, HMOs and Other Managed Care Programs

Policy Clarifications for OnabotulinumtoxinA (Botox®) and Other Botulinum Toxins

This *ForwardHealth Update* clarifies current policy for the use of botulinum toxins, including OnabotulinumtoxinA (Botox®).

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General Information for Use of Botulinum Toxins

There are currently four botulinum toxin products commercially available in the United States:

- OnabotulinumtoxinA.
- Rimabotulinumtoxin.
- AbobotulinumtoxinA.
- IncobotulinumtoxinA.

Each preparation has distinct pharmacological and clinical profiles.

Dosing patterns are specific to the preparation of neurotoxin and are very different between different serotypes. Failure to recognize the unique characteristics of each formulation of botulinum toxin can lead to undesired patient outcomes. It is expected that prescribers will be familiar with and experienced in the use of these agents and will use evidence-based medicine to select the appropriate drug and dose regimen for each patient condition.

All botulinum toxin products are diagnosis-restricted drugs. Botulinum toxins are covered without prior authorization (PA) for any of the diagnoses listed on the Diagnosis Code-Restricted Physician-Administered Drugs data table on the Physicians page, located in the Provider Specific Resources section of the ForwardHealth Portal at www.forwardhealth.wi.gov/. The table lists ForwardHealth-approved diagnoses with their corresponding *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) diagnosis codes. Uses of botulinum toxins for diagnoses not on the table require submission of a PA request.

Submitting Prior Authorization Requests for Botulinum Toxins to Treat Other Diagnoses

The following must be submitted to request PA for a botulinum toxin for a diagnosis not on the Diagnosis Code-Restricted Physician-Administered Drugs data table (with the exception of chronic migraines — refer to the Clarifications to the Coverage of Botox® to Treat Chronic Migraines section of this *Update*):

- A completed Prior Authorization Request Form (PA/RF), F-11018 (05/13).
- A completed Prior Authorization/“J” Code Attachment (PA/JCA), F-11034 (07/12).

In addition to the PA request forms, providers are required to submit peer-reviewed medical literature to support the

proven efficacy of the botulinum toxin for the specific condition that is to be treated.

The PA/RF and PA/JCA can be found on the Forms page of the ForwardHealth Portal at www.forwardhealth.wi.gov/. Providers may refer to the Prior Authorization Portal User Guide available on the Providers area of the Portal for instructions on submitting PA requests and uploading documentation.

Providers may also submit PA requests to ForwardHealth by fax at (608) 221-8616 or by mail to the following address:

ForwardHealth
Prior Authorization
Ste 88
313 Blettner Blvd
Madison WI 53784

For complete PA information, refer to the Physician service area of the Online Handbook.

Policy Clarifications for OnabotulinumtoxinA (Botox®)

As originally published in the February 2013 *Update* (2013-14), titled “Policy for OnabotulinumtoxinA (Botox®),” Botox® will continue to be covered for BadgerCare Plus Standard Plan, BadgerCare Plus Benchmark Plan, BadgerCare Plus Core Plan, and Medicaid members. It is *not* covered for BadgerCare Plus Basic Plan or SeniorCare members.

For members enrolled in BadgerCare Plus HMOs, Medicaid SSI HMOs, and most special managed care programs, claims for Botox® should continue to be submitted to BadgerCare Plus and Medicaid fee-for-service for reimbursement.

Clarifications to the Coverage of Botox® to Treat Chronic Migraines

The administration of Botox® is no longer limited to neurologists as of August 1, 2013. The following licensed

and Medicaid-enrolled providers familiar with and experienced in the use of Botox® may administer this agent to treat *chronic* migraines:

- Nurse practitioners.
- Physician assistants.
- Physicians.

Botox® for use to treat chronic migraines will continue to require PA requested by the rendering provider on the Prior Authorization Drug Attachment for OnabotulinumtoxinA (Botox®) to Treat Chronic Migraines form, F-00701 (08/13). This form must be used to request PA for Botox® to treat chronic migraines and must be filled out completely. It is not necessary for providers to submit additional clinical documentation with the Prior Authorization Drug Attachment for OnabotulinumtoxinA (Botox®) to Treat Chronic Migraines form, unless requested by ForwardHealth. Unusual situations may be summarized using the space in Element 25. Incomplete PA requests will be returned or denied. The form and instructions have been revised and are included in Attachments 1 and 2 of this *Update*.

In addition, a dosing range of 155-195 units is considered acceptable for the use of Botox® to treat chronic migraines.

Clarifications to the Coverage of Botox® to Treat Urinary Incontinence

Effective for date of service (DOS) on and after August 1, 2013, OnabotulinumtoxinA (Botox®) may be used to treat urinary incontinence, regardless of setting, without a PA.

Clarifications to the Claims Submission Process for Botox® to Treat Urinary Incontinence

Botox® for urinary incontinence billed on a professional claim is diagnosis-restricted. Refer to the Diagnosis Code-Restricted Physician-Administered Drugs data table on the Physicians page, located in the Provider Specific Resources section of the Providers area of the ForwardHealth Portal at www.forwardhealth.wi.gov/. The table lists ForwardHealth-

approved diagnoses related to urinary incontinence with their corresponding ICD-9-CM diagnosis codes.

Prescribing/Referring/Ordering Providers Are Required to Be Medicaid-Enrolled

As a reminder, all physicians and other professionals who prescribe, refer, or order services for Wisconsin Medicaid and BadgerCare Plus members on and after July 15, 2013, are required to be Medicaid-enrolled. Prior authorization requests received on and after July 15, 2013, and claims for DOS on and after July 15, 2013, for services that are prescribed, referred, or ordered will be returned or denied if they do not include the National Provider Identifier of a Medicaid-enrolled provider. For more information about enrollment options and new requirements for prescribing/referring/ordering providers, refer to the June 2013 *Update* (2013-34), titled “New Requirements for Prescribing/Referring/Ordering Providers Due to the Affordable Care Act.”

Information Regarding Managed Care Organizations

This *Update* contains fee-for-service policy and applies to services members receive on a fee-for-service basis only. For managed care policy, contact the appropriate managed care organization. Managed care organizations are required to provide at least the same benefits as those provided under fee-for-service arrangements.

The *ForwardHealth Update* is the first source of program policy and billing information for providers.

Wisconsin Medicaid, BadgerCare Plus, SeniorCare, and Wisconsin Chronic Disease Program are administered by the Division of Health Care Access and Accountability, Wisconsin Department of Health Services (DHS). The Wisconsin AIDS/HIV Drug Assistance Program and the Wisconsin Well Woman Program are administered by the Division of Public Health, Wisconsin DHS.

For questions, call Provider Services at (800) 947-9627 or visit our Web site at www.forwardhealth.wi.gov/.

P-1250

ATTACHMENT 1

Prior Authorization Drug Attachment for OnabotulinumtoxinA (Botox[®]) to Treat Chronic Migraines Completion Instructions

(A copy of the “Prior Authorization Drug Attachment for OnabotulinumtoxinA [Botox[®]] to Treat Chronic Migraines Completion Instructions” is located on the following pages.)

FORWARDHEALTH PRIOR AUTHORIZATION DRUG ATTACHMENT FOR ONABOTULINUMTOXINA (BOTOX®) TO TREAT CHRONIC MIGRAINES COMPLETION INSTRUCTIONS

ForwardHealth requires certain information to enable the programs to authorize and pay for medical services provided to eligible members.

Members of ForwardHealth are required to give providers full, correct, and truthful information for the submission of correct and complete claims for reimbursement. This information should include, but is not limited to, information concerning enrollment status, accurate name, address, and member identification number (DHS 104.02[4], Wis. Admin. Code).

Under s. 49.45(4), Wis. Stats., personally identifiable information about program applicants and members is confidential and is used for purposes directly related to ForwardHealth administration such as determining eligibility of the applicant, processing prior authorization (PA) requests, or processing provider claims for reimbursement. Failure to supply the information requested by the form may result in denial of PA or payment for the services. Providers are expected to be able to make available upon request clinical documentation supporting all information submitted on this form.

Rendering providers are required to use this form when requesting PA for OnabotulinumtoxinA (Botox®) to treat chronic migraines. If necessary, attach additional pages if more space is needed. Refer to the applicable service-specific publications for service restrictions and additional documentation requirements. Provide enough information for ForwardHealth to make a determination about the request.

Rendering providers may submit PA requests on the Prior Authorization Drug Attachment for OnabotulinumtoxinA (Botox®) to Treat Chronic Migraines form, F-00701, in one of the following ways:

- 1) For requests submitted on the ForwardHealth Portal, rendering providers can access www.forwardhealth.wi.gov/.
- 2) For requests submitted by fax, rendering providers should submit a Prior Authorization Request Form (PA/RF), F-11018, and the Prior Authorization Drug Attachment for OnabotulinumtoxinA (Botox®) to Treat Chronic Migraines, F-00701, to ForwardHealth at (608) 221-8616.
- 3) For requests submitted by mail, rendering providers should send a PA/RF and the Prior Authorization Drug Attachment for OnabotulinumtoxinA (Botox®) to Treat Chronic Migraines form to the following address:

ForwardHealth
Prior Authorization
Ste 88
313 Blettner Blvd
Madison WI 53784

Rendering providers should make duplicate copies of all paper documents mailed to ForwardHealth. The provision of services that are greater than or significantly different from those authorized may result in nonpayment of the billing claim(s).

SECTION I — MEMBER AND PROVIDER INFORMATION

Element 1 — Name — Member

Enter the member's last name, first name, and middle initial. Use Wisconsin's Enrollment Verification System (EVS) to obtain the correct spelling of the member's name. If the name or spelling of the name on the ForwardHealth identification card and the EVS do not match, use the spelling from the EVS.

Element 2 — Member Identification Number

Enter the member ID. Do not enter any other numbers or letters.

Element 3 — Date of Birth — Member

Enter the member's date of birth in MM/DD/CCYY format.

Element 4 — Name — Rendering Provider

Enter the name of the rendering provider ordering the service for which PA is being requested.

Element 5 — National Provider Identifier (NPI) — Rendering Provider

Enter the rendering provider's 10-digit National Provider Identifier (NPI).

Element 6 — Address — Rendering Provider

Enter the address (street, city, state, and ZIP+4 code) of the rendering provider.

Element 7 — Telephone Number — Rendering Provider

Enter the telephone number, including area code, of the rendering provider.

Element 8 — Name — Billing Provider

Enter the name of the billing provider.

Element 9 — NPI — Billing Provider

Enter the billing provider's NPI.

SECTION II — DRUG ORDER INFORMATION

Element 10 — Drug Name

This element is populated with OnabotulinumtoxinA (Botox®).

Element 11 — HCPCS Drug Code

This element is populated with J0585.

Element 12 — Treatment Dose (In Units)

Enter the number of units of Botox® that will be administered per treatment.

Element 13 — Frequency of Treatments

Enter the frequency with which the member will receive Botox® treatments.

Element 14 — Units to Be Billed Per Treatment

Enter the number of units of Botox® that will be billed per treatment (the units administered plus the units wasted).

SECTIONS III, IV, or V

Rendering providers are required to complete *one* of Section III, IV, or V.

SECTION III — CLINICAL INFORMATION FOR BOTOX® — INITIAL REQUEST ONLY

Element 15

Indicate whether or not the member is 18 years of age or older.

Element 16

Indicate whether or not the rendering provider has evaluated the member and diagnosed the member as experiencing chronic migraines using the Revised International Headache Society criteria for chronic migraines.

Element 17

Indicate whether or not the member has experienced headaches (tension-type and/or migraine) for **three or more** months that have lasted **four or more** hours per day on **15 or more** days per month, with **eight or more** headache days per month being migraines/probable migraines (and that are not due to medication overuse or attributed to another causative disorder).

Element 18

Indicate whether or not the member scored a grade indicating moderate to severe disability on the Migraine Disability Assessment (MIDAS) test or on a similar validated tool.

Element 19

Indicate whether or not the rendering provider has discussed alternative nonpharmacological treatment options with the member, such as behavioral therapies, physical therapies, and lifestyle modifications.

Element 20

Check the boxes next to the drug categories from which the member has tried migraine prophylaxis medications. In the space provided, document the names of the medications tried, the approximate dates the medications were received, and specific details about the treatment results, including if the medications resulted in an unsatisfactory therapeutic response or a clinically significant adverse drug reaction.

Indicate whether or not the member has tried migraine prophylaxis medications from **three or more** of the drug categories listed. If "no," indicate whether or not the member has a medical condition that prevents him or her from trying migraine prophylaxis medications from **three or more** of the drug categories listed, or indicate whether or not there is a clinically significant drug interaction with a medication the member is currently taking that prevents him or her from trying migraine prophylaxis medications from **three or more** of the drug categories listed. Document specific details about the member's medical condition or the clinically significant drug interaction in the space provided.

SECTION IV — CLINICAL INFORMATION FOR BOTOX® — FIRST RENEWAL REQUEST ONLY (Following Initial Approval Only)

Complete this section for first renewal requests for Botox®, following approval of an initial PA request for Botox®.

Element 21

Indicate whether or not the member has experienced clinically significant and documented improvement in the frequency or duration of chronic migraines using at least **one** of the indicators listed. If “yes,” check all of the indicators that apply. If “no,” explain the medical necessity for further treatment.

SECTION V — CLINICAL INFORMATION FOR BOTOX® — SUBSEQUENT RENEWAL REQUEST ONLY (Following First Renewal Approval Only)

Complete this section for subsequent renewal requests for Botox®, following approval of a first renewal PA request for Botox®.

Element 22

Indicate whether or not the member **continues to experience** the previously documented clinically significant improvement in the frequency or duration of chronic migraines as a result of Botox® treatment. If “no,” explain the medical necessity for further treatment.

SECTION VI — ATTESTATION AND AUTHORIZED SIGNATURE

Element 23 — Signature — Rendering Provider

The rendering provider is required to complete and sign this form.

Element 24 — Date Signed — Rendering Provider

Enter the month, day, and year the form was signed by the rendering provider in MM/DD/CCYY format.

SECTION VII — ADDITIONAL INFORMATION

Element 25

Indicate any additional information in the space provided. Additional diagnostic and clinical information explaining the need for the product requested may be included here.

ATTACHMENT 2
Prior Authorization Drug Attachment for
OnabotulinumtoxinA (Botox®) to
Treat Chronic Migraines

(A copy of the “Prior Authorization Drug Attachment for OnabotulinumtoxinA [Botox®] to Treat Chronic Migraines” form is located on the following pages.)

FORWARDHEALTH
**PRIOR AUTHORIZATION DRUG ATTACHMENT FOR ONABOTULINUMTOXINA (BOTOX®)
TO TREAT CHRONIC MIGRAINES**

Instructions: Type or print clearly. Before completing this form, refer to the Prior Authorization Drug Attachment for OnabotulinumtoxinA (Botox®) to Treat Chronic Migraines Completion Instructions, F-00701A.

SECTION I — MEMBER AND PROVIDER INFORMATION

1. Name — Member (Last, First, Middle Initial)

2. Member Identification Number

3. Date of Birth — Member

4. Name — Rendering Provider

5. National Provider Identifier (NPI) — Rendering Provider

6. Address — Rendering Provider (Street, City, State, ZIP+4 Code)

7. Telephone Number — Rendering Provider

8. Name — Billing Provider

9. NPI — Billing Provider

SECTION II — DRUG ORDER INFORMATION

10. Drug Name

OnabotulinumtoxinA (Botox®)

11. HCPCS Drug Code

J0585

12. Treatment Dose (In Units)

13. Frequency of Treatments

14. Units to Be Billed Per Treatment

SECTION III — CLINICAL INFORMATION FOR BOTOX® — INITIAL REQUEST ONLY

15. Is the member 18 years of age or older?

Yes No

16. Has the rendering provider evaluated the member and diagnosed the member as experiencing chronic migraines using the Revised International Headache Society criteria for chronic migraines?

Yes No

17. Has the member experienced headaches (tension-type and/or migraine) for **three or more** months that have lasted **four or more** hours per day on **15 or more** days per month, with **eight or more** headache days per month being migraines / probable migraines (and that are not due to medication overuse or attributed to another causative disorder)?

Yes No

18. Did the member score a grade indicating moderate to severe disability on the Migraine Disability Assessment (MIDAS) test or on a similar validated tool?

Yes No

19. Has the rendering provider discussed alternative nonpharmacological treatment options with the member, such as behavioral therapies, physical therapies, and lifestyle modifications?

Yes No

Continued



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SECTION III — CLINICAL INFORMATION FOR BOTOX® — INITIAL REQUEST ONLY (Continued)

20. Check the boxes next to the drug categories from which the member has tried migraine prophylaxis medications. In the space provided, document the following:

- The names of the medications tried.
- The approximate dates the medications were received.
- Specific details about the treatment results, including if the medications resulted in an unsatisfactory therapeutic response or a clinically significant adverse drug reaction.

1. Antidepressants _____

2. Anticonvulsants _____

3. Beta blockers _____

4. Calcium channel blockers _____

5. Other drugs _____

Has the member tried migraine prophylaxis medications from **three or more** of the drug categories listed above?

Yes No

If not, does the member have a medical condition that prevents him or her from trying migraine prophylaxis medications from **three or more** of the drug categories listed above, or is there a clinically significant drug interaction with a medication the member is currently taking that prevents him or her from trying migraine prophylaxis medications from **three or more** of the drug categories listed above?

Yes No

Document specific details about the member's medical condition or the clinically significant drug interaction.

SECTION IV — CLINICAL INFORMATION FOR BOTOX® — FIRST RENEWAL REQUEST ONLY (Following Initial Approval Only)

21. Has the member experienced clinically significant and documented improvement in the frequency or duration of chronic migraines using at least **one** of the indicators below? Yes No

If yes, check all that apply.

- Reduction in acute services, emergency services, or need for rescue treatment for acute chronic migraines.
- At least a 40 percent reduction in the frequency, severity, or length of chronic migraines.
- Improved assessment score on MIDAS test, or on similar validated tool.
- Reduced use of analgesics.

If no, explain the medical necessity for further treatment.

SECTION V — CLINICAL INFORMATION FOR BOTOX® — SUBSEQUENT RENEWAL REQUESTS ONLY (Following First Renewal Approval Only)

22. Does the member **continue to experience** the previously documented clinically significant improvement in the frequency or duration of chronic migraines as a result of Botox® treatment? Yes No

If no, explain the medical necessity for further treatment.

SECTION VI — ATTESTATION AND AUTHORIZED SIGNATURE

23. **SIGNATURE** — Rendering Provider

24. Date Signed — Rendering Provider

SECTION VII — ADDITIONAL INFORMATION

25. Include any additional information in the space below. Additional diagnostic and clinical information explaining the need for the product requested may be included here.