Office of Workers' Compensation Programs Division of Federal Employees' Compensation



# Authorization Request form and Certification/Letter of Medical Necessity for Compounded Drugs.

OMB No. 1240-0055 Expires: 05/31/2024

This form is to be completed and signed by the patient's treating physician for any compounded drug. A compounded drug is a combination of two or more drugs prepared by a pharmacist to meet the patient's individual needs. Complete all sections of this form. Failure to complete this form in its entirety may result in delayed processing or an adverse determination for insufficient information. The form is valid and effective for up to 90 days following the date of the treating physician's signature/certification.

Part A - Patient Information							
1. Patient Name (Last, First, Middle Initial):			2. Patient OWCP #:				
3. Street Address:			4. Date of Birth (mm/dd/yyyy):				
5. City:	6. State:	7. Zip:	8. Phone #:				
Part B - Treating Physician Information							
9. Treating Physician Name:			10. Treating Physician NPI#:				
11. Street Address:		12. Provider ID#:					
13. City:	14. State:	15. Zip:	16. Phone #:	17. Secure Fax #:			
Part C - Compounded Drug	Information						
18. Medication Name:			19. Primary Diagnosis:	20. ICD-10 Code:			
21. Direction for use (for 90-day period or less):			22. Date of Last Physical Examination (mm/dd/yyyy):				
23. Route of Administration (and Code):	Oral (1)		24. Anticipated Length of Therapy:  30 days				
	☐ Topical (5)		☐ 60 days				
	Injection (2)		☐ 90 days				
	☐ Other (specify route ☐ and code):		☐ Other (specify):				
Part D - Certification of Med	lical Necess	ity	l				
25. Has the patient tried and failed to obtain relief through over-the-counter or other Yes No prescribed products for the diagnosis provided? If no, explain below in item 30.							
26. Are there commercially available FDA-approved drugs appropriate for the diagnosis?  Yes No							

27. Are all of the active ingredients of the compounded drug FDA-approved for the		
diagnosis provided? If no, please explain below in item number 30.	🗌 Yes 🗌 No	

28. Complete the following for each active and inactive ingredient in the compounded drug; IF MORE THAN TEN ACTIVE/INACTIVE INGREDIENTS ARE BEING USED, LIST (INCLUDING NAME, NDC, QUANTITY, STRENGTH, AND MEDICAL NECESSITY FOR EACH) AND EXPLAIN THE NEED FOR MORE THAN TEN IN ITEM NUMBER 30. Only the most cost effective and medically necessary ingredients should be used. Herbal supplements, such as resveratrol, lavender oil, and alpha-lipoic acid, cannot be authorized on this form and will cause the form to be returned to the provider. Herbal supplements are authorized only on an exception basis on approval by the OWCP Chief Medical Officer or his/her designee.

	Drug Name:	NDC:	Quantity:	Strength:	Medically Necessary?
Ingredient #1					🗌 Yes 🗌 No
Ingredient #2					🗌 Yes 🗌 No
Ingredient #3					🗌 Yes 🗌 No
Ingredient #4					🗌 Yes 🗌 No
Ingredient #5					🗌 Yes 🗌 No
Ingredient #6					🗌 Yes 🗌 No
Ingredient #7					🗌 Yes 🗌 No
Ingredient #8					🗌 Yes 🗌 No
Ingredient #9					🗌 Yes 🗌 No
Ingredient #10					🗌 Yes 🗌 No

29. Is the compounded drug medically necessary for its intended use?

🗌 Yes 🗌 No

30. Provide a narrative explaining why the compounded drug is medically necessary, including why no commercially available (non-compounded) drug is sufficient. You may cite relevant medical literature to support your opinion. You may be asked to provide clinical documentation and other relevant evidence to support use of this medication including demonstrated improvement in both pain and function. The need for this medication is subject to review by claims staff and medical professionals. See instructions on item 28 if the compounded drug has more than ten ingredients.

I certify that I am the treating physician for the above-named patient and that the medication requested is medically necessary and cost effective for the patient. I further certify, under penalty of law, that the information provided on this form is true and correct to the best of my knowledge, and that documentation supporting this information is available for review if requested. I understand that any person who knowingly makes any false statement or misrepresentation to obtain prescription drugs from OWCP is subject to administrative penalties including provider exclusion; civil penalties including those under the False Claims Act and/or criminal prosecution. The submission of this form signifies my certification of the above and the on-file signature on my provider enrollment form is hereby incorporated by reference.

31. Signature/CERTIFICATION of Patient's Treating Physician:

Yes 32. Date

#### Instructions

#### **PART A - Patient Information**

- 1. Provide the patient's name in this order: last name, first name, middle initial.
- Provide the patient's Office of Workers' Compensation Programs (OWCP) claim number. The OWCP claim number is the unique 9-digit number that OWCP assigns to the patient's (claimant's) workers' compensation claim.
- 3. Provide the street address of the patient's residence (with unit or apartment number, if applicable).
- 4. Provide the patient's date of birth, including the month, date, and year.
- 5. Provide the city where the patient's residence is located.
- 6. Provide the state where the patient's residence is located.
- 7. Provide the zip code where the patient's residence is located.
- 8. Provide the patient's phone number.

### **PART B - Treating Physician Information**

- 9. Provide the treating physician's name.
- 10. Provide the treating physician's National Provider Identifier (NPI) number. The NPI number is a unique, 10digit identification number issued to health care providers in the United States by the Centers for Medicare and Medicaid Services (CMS).
- 11. Provide the street address of the treating physician's office (with unit or suite number, if applicable).
- 12. Provide the treating physician's Provider ID number. The Provider ID number is the 9-digit identification number assigned to health care providers enrolled in OWCP's Web Bill Processing Portal.
- 13. Provide the city where the treating physician's office is located.
- 14. Provide the state where the treating physician's office is located.
- 15. Provide the zip code where the treating physician's office is located.
- 16. Provide the treating physician's office telephone number.
- 17. Provide the treating physician's secure office fax number. A secure fax line is one that meets or exceeds the requirements for HIPAA privacy and security.

# PART C - Compounded Drug Information

- 18. Provide the name, if any, of the compounded drug prescribed by the patient's treating physician, including the name, description, or terms utilized by the treating physician to identify the compounded drug. If the compounded drug does not have a name, provide "Compounded Drug Unique."
- 19. Provide the patient's primary diagnosis that warrants the compounded drug prescribed.
- 20. Provide the ICD-10 code for the primary diagnosis. The International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) is a coding of diseases, signs, and symptoms, abnormal findings, complaints, social circumstances and external causes of injury or diseases, as classified by the World Health Organization. The code set allows more than 14,400 different codes and permits the tracking of diagnoses.
- 21. Provide the direction of the compounded drug prescribed. The direction of a medication is the amount and rate of occurrence at which the drug is given (e.g. 1 tablet every 12 hours). **The prescription must be limited to a 30-day or less supply.**
- 22. Provide the date at which the treating physician last conducted a medical examination of the patient. The medical examination must have been in person and have occurred within 2 weeks of the date of signature on this form.
- 23. Mark an "X" next to the applicable route of administration if it is oral, topical, or by injection. If the route of administration is not oral, topical, or by injection, mark "other" and specify the manner of administration and Route Code. For example: Intravenous (A); Buccal (B); Intramuscular (C); Dental (D); Perfusion (F); Inhalation (H); Translingual (L); Miscellaneous (M); Intraperitoneal (P); Irrigation (R); Sublingual (S);

Transdermal (T); Urethral (U); Vaginal (V); Rectal (3); Mucous Membrane (4); Ophthalmic (6); Nasal (7); Otic (8); Intradermal (9).

24. Mark an "X" next to "30 days," "60 days," or "90 days" to indicate the anticipated length of treatment; if shorter than 30 days or longer than 90 days, mark "other" and specify the anticipated length of treatment.

# PART D Certification of Medical Necessity - Responses are Mandatory

- 25. Mark "yes" or "no" to the question. If "no," explain in item 30.
- 26. Mark "yes" or "no" to the question.
- 27. Mark "yes" or "no" to the question. If "no," explain in item 30.
- 28. List each active and inactive ingredient in the compounded drug by name, National Drug Code (NDC), quantity, and strength, and mark "yes" or "no" to the question of whether the ingredient is medically necessary. The NDC is a unique, three-segment number that serves as a universal product identifier for drugs. The quantity must be expressed in units such as milligrams, micrograms, drops, etc. The strength is the amount of drug in a given dosage form (e.g. 500 mg/tablet). Each ingredient (active and any inactive ingredient with an NDC code for which payment is sought) in the compounded drug must be medically necessary for treatment and for delivery of the compounded drug, and should be at the lowest possible cost to perform its function.
- 29. Mark "yes" or "no" as to whether the compounded drug prescribed is medically necessary.
- 30. Provide a narrative that explains why the compounded drug prescribed is medically necessary, including why no commercially available (non-compounded) drug is sufficient. You may cite relevant medical literature to support your opinion. The information on this form, including the narrative, is subject to review by claims staff and medical personnel. The treating physician submitting the form may be asked to provide additional documentation in support of his/her certification of medical necessity. Ingredients beyond ten must also be listed here with all information required in item 28.
- 31. Affirm the treating physician's signature/certification by marking an "X" in the box.
- 32. Provide the date of the treating physician's signature/certification.

#### Public Burden Statement

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. If you have any comments regarding the burden estimate or any other aspect to this collection of information, including suggestions for reducing this burden, send them to the Office of Workers' Compensation Programs, U.S. Department of Labor, Room S3524, 200 Constitution Avenue, N.W., Washington, D.C. 20210. Do not submit the completed claim form to this address. Persons are not required to respond to this information collection unless it displays a currently valid OMB number.

# Privacy Act Statement

In accordance with the Privacy Act of 1974, as amended (5 U.S.C. 552a), you are hereby notified that: (1) The Federal Employees' Compensation Act (FECA), as amended and extended (5 U.S.C. 8101, et seq.) is administered by the Office of Workers' Compensation Programs of the U.S. Department of Labor, which receives and maintains personal information on claimants and their immediate families. (2) Information which the Office has will be used to determine eligibility for and the amount of benefits payable under the FECA, and may be verified through computer matches or other appropriate means. (3) Information may be given to the Federal agency which employed the claimant at the time of injury in order to verify statements made, answer questions concerning the status of the claim, verify billing, and to consider issues relating to entitlement to benefits or other relevant matters. (4) Information may be given to Federal, state and local agencies for law enforcement purposes, to obtain information relevant to a decision under the FECA, to determine whether benefits are being paid properly, including whether prohibited dual payments are being made, and, where appropriate, to pursue salary/administrative offset and debt collection actions required or permitted by the FECA and/or the Debt Collection Act. (5) Failure to disclose all requested information may delay the processing of the claim or the payment of benefits, or may result in an unfavorable decision or reduced level of benefits.

#### Notice

If you have a disability, Federal law gives you the right to receive help from the OWCP/DFEC in the form of communication assistance, accommodation(s) and modification(s) to aid you. For example, OWCP/DFEC will provide you with the copies of documents in alternate formats, communication services such as sign language interpretation, or other kinds of adjustments or changes to accommodate your disability. Please contact OWCP/DFEC to ask about this assistance.