KERN HEALTH SYSTEMS

KERN HEALTH SYSTEMS POLICY AND PROCEDURES					
SUBJECT: Drug Utilization and Non-Formulary Treatment Request				POLICY #: 13.01-P	
DEPARTMENT: Pharmacy					
Effective Date: 08/1997	Review/Revised Date: 2/8/2024	DMHC	X	PAC	
		DHCS	X	QI/UM COMMITTEE	
		BOD		FINANCE COMMITTEE	

_____ Date _____
Emily Duran
Chief Executive Officer

_____ Date _____
Chief Medical Officer

_____ Date _____
Director of Pharmacy

POLICY:
The following applies to pharmacy authorization requests that will be billed on a pharmacy NCPDP claim prior to the launch of Medi-Cal Rx and those medical supplies and devices remaining with the managed care plans outlined by the Medi- Cal Rx Scope document. All NCPDP pharmacy requests for claims for date of service after the launch of Medi-Cal Rx will be directed to Medi-Cal Rx for review. Until that time, these policies and protocols effectuated by Kern Health Systems will remain unchanged and in place. Institutional and professional claims will continue to be processed by the managed care plan and therefore the requests would follow these procedures outlined. Those drugs, medical supplies and devices will be reviewed as stated in this policy and the encounters submitted on an 837P file.

All non-formulary medications or formulas require prior authorization. Physician Administered Drugs (PADs) will be managed by a No Prior Authorization List. All PAD and similar not listed require prior authorization. All medically necessary outpatient prescription drugs, except for those specifically excluded from the Medi-Cal contract, shall be available to KHS Medi-Cal members.[1] This determination will be made through the non-formulary treatment request process as outlined in this policy and procedure.

The non-formulary treatment request process will conform to the requirements outlined in the following statutory, regulatory, and contractual sources:

- Code of Federal Regulations Title 42 §§431.211; 431.213; and 431.214
- California Health and Safety Code §§ 1367.01[2]; 1367.21; 1367.22; 1367.24
- California Welfare and Institutions Code §14185
- CCR Title 28 §1300.67.24
- CCR Title 22 §§ 51003; 51014.1; 51014.2; 53854; 53894
- DHS Contract Exhibit A - Attachment 5 (3)(F); Exhibit A –Attachment 10 (7)(F)
- DHS MMCD Letters 04006 (November 1, 2004) and 05005 (April 11, 2005), and 08-013 (December 16, 2008).

This document shall be disclosed to the public upon request.[3]

DEFINITIONS:

Chronic and Seriously Debilitating[4]	Diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.
Life Threatening[5]	Diseases or conditions (1) where the likelihood of death is high unless the course of the disease is interrupted and/or (2) with potentially fatal outcomes where the endpoint of clinical intervention is survival.

PROCEDURES:

1.0 SUBMISSION OF A NON-FORMULARY DRUG REQUEST

Non-Formulary drug requests can be made by KHS providers electronically via the secure KHS portal or on a *61-211 Form* if one does not have access to the KHS Provider Portal. Portal submission is the preferred method. (See Attachment A). Form should be mailed/faxed to the following location:

KHS Pharmacy Department
2900 Buck Owens Boulevard
Bakersfield, CA 93308
661-664-5191

Staffing availability and working hours are Monday thru Friday 8:00 am to 5:00 pm except holiday for inbound collect, or toll-free calls regarding review requests. After business hours 24-hour Telephone Triage Line (661)-632-1590 (Bakersfield) or 1-800-391-2000 (outside Bakersfield) (TTY 711).

Staff representative will state his/her name, title, and calling from Kern Family Health Care/ Kern Health Systems when initiating or returning calls.

KHS only requests information reasonably necessary to make a decision regarding the request.[6] Documentation must be complete and include:

A. Patient name.

B. CIN number.
C. Diagnosis with brief history.
D. Reason for request/justification including formulary medication failures.
E. Drug name, strength, directions, and National Drug Code.
F. Prescriber's name.

2.0 REVIEW OF TAR

Incoming requests are date and time stamped. Requests not submitted via the Provider Portal are formatted and data entered by staff. The initial gathering of information and preliminary decision is worked up by pharmacy technicians and forwarded to pharmacists or medical directors for review. All medical necessity determinations are made by the pharmacist or medical director. The Notice of Action (NOA) Letter is created as necessary. If needing to be translated, the NOA Letter is sent to the Cultural & Linguistics Team. TAR review includes the actions outlined in the following table.

Action	Timeline	Comments
Review by Pharmacist or MD		Evaluation for medical necessity denials signed by licensed pharmacist or MD[7]
Decision (approve or deny)	Within 24 hours of receipt[8].	

Medications and supplies are evaluated based on appropriateness, efficacy, safety, pharmacokinetics and cost effectiveness. Authorization may be granted only for Medi-Cal benefits that are medically necessary and do not exceed health care services received by the public generally for similar medical conditions. Authorizations may be granted only for the lowest cost item or service covered by the Medi-Cal program that meets the member's medical need.[9]

3.0 PRACTITIONER/PROVIDER AND MEMBER NOTIFICATION

Results of the TAR review are communicated by Pharmacy staff to the practitioner/provider and member as outlined in the following table. Notification to providers is provided via portal or facsimile if possible. The notification confirmation is attached to the request. If notice by electronic portal or facsimile is not possible, verbal notice is provided via phone within 24 hours of receipt. In such cases, written notice follows as outlined in the table below.

Result of Review	Practitioner/Provider Notice	Member Notice
Approved	Approved form[10] (within 24 hours of receipt). [11]	
Denied	Denied form (within 24 hours of receipt).[12]	*Notice of Action Documents* (within 2 business days of the decision). [13] Documents include all of the following: ❖ *Notice of Action – Denial* (Attachments B) *Your Rights Under Medi-Cal Managed Care & Form*

Result of Review	Practitioner/Provider Notice	Member Notice
		to File a State Hearing. Medi-Cal members only.

Notice of Action letters together with the indicated enclosures contain all the required elements for both provider and member notice of delay, denial, or modification including the following[14]:

A. The action taken.
B. A clear and concise explanation of the reason for the decision (including clinical reasons for decisions regarding medical necessity).
C. A description of the criteria/guidelines used. Providers may request a copy of the criteria used. Requests may be made by mail, fax, email, in person at the KHS administrative offices, or telephone. KHS will mail the criteria to those providers who do not have fax, email, or internet access. The criteria used are:
    1. Food and Drug Administration (FDA) approved indications
    2. Medi-Cal coverage considerations
    3. National professional guidelines are used when applicable. (GINA, AACE, AHA, Etc.)
    4. Tertiary professional reviews are used as needed. (MCG, UpToDate, etc.)
    5. CMS excluded drug categories are applied when applicable to Medicaid plans.
D. A citation of the specific regulations or plan authorization procedures supporting the action[15].
E. Information on how to file a grievance or an appeal for a denied/modified service with KHS including the Plan's name address and phone number.
F. Information regarding a Medi-Cal member's right to a State Fair Hearing including:
    1. The method by which a hearing may be obtained.
    2. That the member may either be self- represented or represented by an authorized third party such as legal counsel, relative, friend, or any other person.
    3. The time limit for requesting a fair hearing.
    4. The toll-free number for obtaining information on legal service organizations for representation.
G. Nondiscrimination Notice.
H. Language Assistance Taglines.
I. Information regarding the member's right to an Independent Medical Review with DMHC.
J. DMHC required language regarding grievances[16].
K. Name and telephone number of the pharmacy department.

4.0 DOCUMENTATION

Letters regarding authorization requests, including those sent by KHS to both members and providers, are retained as outlined in *KHS Policy and Procedure #14.53-I – Records Retention.*[17]

5.0 ALLOWED SUPPLIES OF MEDICATION

Members may receive up to a 30-day supply of medication. Women may receive up to 365-

day supply of hormonal contraceptives.

5.1 Emergency Supplies[18]

During weekends, holidays and non-business hours a pharmacy may choose to dispense enough medication (72 hours supply maximum) as an emergency supply to the member until the next working day, at the dispensing pharmacist's discretion according to pharmacy policy and procedures as defined by Title 22 section 51056[19]. If the medication is not on the Plan Formulary, a request must be submitted for payment processing stating the emergency and relevant clinical information about the member's condition and why they were considered immediately necessary, and medication dispensed. A mere statement that an emergency existed is not sufficient. It must be comprehensive enough to support a finding that an emergency existed.[20] TAR approval is not needed for reimbursement before dispensing of 72-hour emergency supply of non-formulary drugs.

5.2 Exclusions

5.2.1 Experimental services are not covered. Investigational services are not covered except when it is clearly documented that all of the following apply:

1) Conventional therapy will not adequately treat the intended member's condition
2) Conventional therapy will not prevent progressive disability or premature death
3) The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service
4) The investigational service is the lowest cost item or service that meets the member's medical needs and is less costly than all conventional alternatives
5) The service is not being performed as a part of a research study protocol
6) There is a reasonable expectation that the investigational service will significantly prolong the intended member's life or will maintain or restore a range of physical and social function suited to activities of daily living.[21]

5.2.2 Services and supplies not primarily medical in purpose or which are common household items are not covered.[22]

5.2.3 The following drugs or categories are limited for coverage:[23]

1. The prescribed use is not for a medically accepted indication.
2. Agents when used for anorexia, weight loss, or weight gain.
3. Agents when used to promote fertility.
4. Agents when used for cosmetic purposes or hair growth.
5. Agents when used for symptomatic relief of cough and colds*.
6. Vitamin and mineral products, except prenatal and fluoride preparations.
7. Nonprescription drugs*.
8. Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
9. Agents when used for the treatment of sexual or erectile dysfunction.
10. Replacement of stolen or lost controlled drugs.

*Exceptions to this rule are specifically listed in formulary, Member Handbook, or Prior Authorization List.

The following are covered services but billed to the State Medicaid program:

1. Psychotherapeutic agents.
2. Alcohol, heroin detoxification, and drug dependency treatment drugs.
3. Antiviral drugs to treat HIV/AIDS.
4. Blood factor products.

Please refer to the Medi-Cal manual under the Two-Plan Model.[24]

6.0 RETROSPECTIVE AUTHORIZATION REQUEST:

Retrospective authorization request may be submitted within sixty (60) calendar days from the date of service for services that are deemed urgent or emergent. All supporting documentation must be included with the request. Any request that requires prior authorization received by KHS with a date of service greater than sixty (60) calendar days will be denied.

All retrospective reviews will be completed within 30 calendar days. KHS will communicate its decision to the provider within 30 days of the receipt of determination, in a manner that is consistent with current law

Failure to obtain prior authorization by the provider due to eligibility verification is not considered urgent or emergent.

6.1 Claim Denials for Services Performed without Obtaining Prior Authorization:

Claims submitted by KHS contract and non-contract providers are matched against authorizations entered into the PBM claims payment system. Providers are required to determine a member's eligibility and obtain prior authorization before initiating non emergent services. If the provider fails to obtain prior authorization or retrospective authorization as defined in 5.0 for non-emergent services, the claim(s) for those services will be denied.

Requests for retrospective payment for unauthorized services may be reviewed at the discretion of the health plan, and the decision to review will be based on the documentation submitted detailing the extenuating circumstances that explains why the prior authorization request was not submitted. All such requests must include complete medical records. Requests for retrospective authorization submitted only with records, will not be reviewed for medical necessity; but, instead denied as prior authorization was not obtained.

Providers may submit a Claims Dispute in accordance with KHS Policy 6.04-P.

7.0 CONTINUITY OF CARE[25]

Medi-Cal members are allowed continued coverage of a non-formulary single source drug which is part of a prescribed therapy previously approved for coverage by the plan for a medical condition of the member and the provider continues to prescribe the drug for the medical condition provided that drug is appropriately prescribed and is considered safe and effective for treating the member's medical condition. Nothing in this section shall preclude the prescribing provider from prescribing another drug covered by the plan that is medically appropriate[26] If previously approved by a plan immediately prior to the date of enrollment, coverage may be continued until the prescribed therapy is no longer prescribed by a contracting practitioner[27]. Approval is contingent upon documentation that the patient had authorization

from the previous plan of the medication at the time of enrollment no more than fifteen (15) days beyond the estimated day supply for the last documented pharmacy fill date.[28]

KHS does not require a new member to repeat step therapy when the member is already being treated for a medical condition by a prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the enrollee's condition. For purposes of this section, "step therapy" means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.

Medi-Cal members are allowed continued coverage of a drug which is removed from the KHS formulary if the drug is part of a prescribed therapy in effect immediately prior to the date of removal until the prescribed therapy is no longer prescribed by a contracting practitioner.

8.0 BRAND NAME MEDICATIONS WHEN EQUIVALENT GENERIC BRAND IS AVAILABLE

If a medication is available or becomes available in an AB rated generic brand, the brand name version will become non-Formulary for KHS.

Unless it is determined to be medically necessary for the patient to continue using the brand name, if a generic brand becomes available during a patient's treatment, the patient will be expected to switch to the generic brand and must fail the generic brand prior to KHS granting authorization for the brand name.

Providers with patients having untoward effects from a generic brand must submit a completed FDA *MedWatch* form to KHS as part of the request for authorization to allow a brand name version instead of a generic brand. (See Attachment F).

Biosimilars and drugs considered as Follow Ons will be treated in the same fashion as if they were a traditional generic of the innovator drug. Per FDA rules, they are not automatically substitutable, but from clinical perspectives they are viewed as a generic version.

9.0 OFF-LABEL USE FOR LIFE THREATENING OR CHRONIC AND SERIOUS CONDITIONS[29]

9.1 Medi-Cal Product

Section does not apply to the Medi-Cal product.[30]

9.2 Peer Reviewed Professional Society Endorsed Supporting Documentation If a physician or other provider wishes to prescribe a non-formulary or restricted FDA approved medication for an off-label use for a life threatening or chronic and debilitating condition, he/she may submit a referral or TAR to the Plan for the same. In the referral, the provider must demonstrate the medication is recognized for the treatment of that condition in one of the following sources:

A. American Hospital Formulary Service's Drug Information.

B. One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(1) The Elsevier Gold Standard's Clinical Pharmacology.

(2) The National Comprehensive Cancer Network Drug and Biologics Compendium.
(3) The Thomson Micromedex DrugDex.

C. Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

The provider is responsible for submitting the required documentation to KHS[31].

10.0 SAMPLE MEDICATIONS[32]

Providers are discouraged from providing samples; however, if samples are given to the member, the entire course of therapy must be covered by the samples. Medications provided as samples do not establish a continuity precedent or satisfy step therapy criteria and, therefore, do not obligate coverage by KHS. If providing samples, Providers shall follow the outlined steps in *KHS Policy and Procedure #13.23-P Pharmaceutical Standards*.

11.0 TRIAL PERIOD[33]

Barring any medically adverse responses from the member, the trial period of a medication shall be determined per the recommended dosing titration guidelines presented to the FDA.

12.0 MONITORING[34]

The Compliance Department will conduct bi-annual audits to monitor compliance of the contracted emergency departments to provide a sufficient quantity of drugs to Medi-Cal members under emergency circumstances to last until the member can reasonably to be expected to have a prescription filled prior to leaving the emergency department. Issues discovered by this monitoring will be brought to the attention of the contracted emergency department and a Corrective Action Plan (CAP) will be required.

ATTACHMENTS:

- Attachment A - Treatment Authorization Request (TAR) Form (61-211)
- Attachment B - Notice of Action – Denial letter
- Attachment C - Notice of Action – Your Rights
- Attachment D - Notice of Action – Nondiscrimination
- Attachment E - Language Assistance Taglines
- Attachment F - MedWatch form

REFERENCE:

Revision 2023-07: NCQA requirement for Language Assistance, staff working hours/availability, and TTY. Expanded process in Section 2, Review per NCQA recommendation. Section 3. C expanded per NCQA recommendation. Per NCQA added language and enhanced sections to accommodate PAD and other drugs billed via medical claims. APL 22-012 provides overall guidance on transition. DHCS File and Use 11/14/2023. **Revision 2022.04:** Policy attachments updated per APL 21-011 and APL 21-004. DMHC approval received on 6/10/2022. DHCS approval received on 7/19/2022.**;** [1]**Revision 2021-07:** Policy revised by Director of Pharmacy regarding changes in pharmacy authorizations and billing. **Revision 2020-02: Revision 2017-07:** Policy revised to comply with CMS Final Rule on prior authorization process. Attachments updated. **Revision 2017-03:** Policy reviewed and updated by Director of Pharmacy. New Section 8.2 provides guidelines for prescribing medication for an off-label use for a life threatening or chronic and debilitating condition. **Revision 2014-10:** Formatting changes to policy, no

material changes. Notice of Action letters (NOAs) revised as a result of the DHCS 2013 Medical Audit ending in 2014- CAF-9. "Your Right's Forms" updated to ensure continued compliance. Translation changes made to comply with MMCD APL 05005. **Revision 2014-04:** Language included in Section 1.0 to add time statement on authorization request. Revised to remove references to Health Families product. **Revision 2013-07:** Reviewed by Director of Pharmacy. Routine revision, updated Section 1.0 regarding submission of treatment authorization request. **Revision 2009-10:** Revision requested by Director of Pharmacy. **Revision 2009-02:** Revised to comply with MMCD Policy Letter 08-013. Notice of Action letters updated with language assistance services notice. **Revision 2007-05:** Revised per DHS/DMHC Medical Audit comment 5/13/2007. **Revision 2007-04** Created Notice of Action Letters for Healthy Families product line per DHS/DMHC Medical Review Audit (YE 10/31/06). **Revision 2005-07:** Reviewed against MMCD Letters 04006 and 05005. New NOAs. **Revision 2005-04:** Continuity of care processes reviewed and revised. Reviewed against DHS Contract 03-76165 (Effective May 1, 2004). **Revision 2004-05:** Revised per DMHC/DHS Medical Audit YE Oct03; finding 1.2. (Addition of member notice of modifications). New single letter for deferral, modification, or denial. **Revision 2002-03**: Revised per DHS comment 01/30/02. **Revision 2002-01:** DHS CAP Verification Visit Report (Med Rev YE 08/00). **Revision 2001-02**: changes made for 2000 Legislation submission – DMHC and DHS/DMHC Medical Review Audit (YE 08/31/00).

[1] HSC 1367.24. CCR Title 22 §53854(d), CCR Title 28 1300.67.24
[2] Applicable to pharmacy per Title 28 §1300.67.24(a)(1)
[3] HSC §1367.01(b)
[4] HSC §1367.21(e)
[5] HSC §1367.21(d)
[6] HSC §1367.01(g)
[7] MMCD Policy Letter 08-013
[8] Social Security Act, Title XIX, Section 1927(a)(5). Per John Kaylen at DHS, allows an extension from 24 hours to 1 business day. Although action must be taken on pain medications for the terminally ill within 72 hours, the Plan must follow the stricter Federal Medicaid 24 hours standard. HSC Section 1367.215. DHS Contract A-5 3(F). Change to comply with CMS Managed Care final Rule Prior Authorization Process (§438.3(s)(6))
[9] CCR Title 22 § 51003
[10] Must include specific service approved (HSC §1367.01(h)(4))
[11] Social Security Act, Title XIX, Section 1927(a)(5). Per John Kaylen at DHS, allows an extension from 24 hours to 1 business day. Although action must be taken on pain medications for the terminally ill within 72 hours, the Plan must follow the stricter Federal Medicaid 24 hours standard. HSC Section 1367.215. HSC §1367.01(h)(3) requires notice to provider within 24 hours of the decision.
[12] Social Security Act, Title XIX, Section 1927(a)(5). Per John Kaylen at DHS, allows an extension from 24 hours to 1 business day. Although action must be taken on pain medications for the terminally ill within 72 hours, the Plan must follow the stricter Federal Medicaid 24 hours standard. HSC Section 1367.215. HSC §1367.01(h)(3) requires notice to provider within 24 hours of the decision. Change to comply with CMS Managed Care final Rule Prior Authorization Process (§438.3(s)(6))
[13] HSC §1367.01(h)(3) has the shortest time period for member notice (2 b/days of decision).CCR Title 22 Section 53894(a) and (d)
[14] HSC §1367.01(h)(4) and (5) and 1367.24(b); CCR Title 22 §53894
[15] Required for member notice only. CCR Title 22 §53894(d)(3)
[16] Required for member notice only. HSC §1367.24(b)
[17] DHS Contract 03-76165 Exhibit A – Attachment 5 (2)(G)
[18] CCR Title 22 §53854(2)
[19] Title 22 51056
[20] Title 22 51056
[21] CCR Title 22 § 51303
[22] CCR Title 22 § 51303
[23] Sec. 1927.[42 U.S.C 1396r-8]
[24] Part 1 Medi-Cal Program Manual MCP: Two-Plan Model
[25] HSC 1367.22
[26] HSC § 1367.22
[27] W&I Code 14185(c)
[28] HSC §1367.22
[29] Health and Safety Code §1367.21
[30] Plan shall reserve the right to modify this.
[31] HSC 1367.21 (b)
[32] Section added upon request of the Director of Pharmacy (3/2/05). Language also included in *Policy 2.24 – Pharmaceutical Guidelines*
[33] Section added upon request of the Director of Pharmacy (3/2/05).

[34] DHS/DMHC Medical Review Audit (YE 10/31/06).

PRESCRIPTION DRUG PRIOR AUTHORIZATION OR STEP THERAPY EXCEPTION REQUEST FORM

Plan/Medical Group Name: _____ **Plan/Medical Group Phone#: (_____)**_____
Plan/Medical Group Fax#: (_____)_____ **Non-Urgent** ☐ **Exigent Circumstances** ☐

Instructions: Please fill out all applicable sections on both pages completely and legibly. Attach any additional documentation that is important for the review, e.g. chart notes or lab data, to support the prior authorization or step-therapy exception request. **Information contained in this form is Protected Health Information under HIPAA.**

Patient Information					
First Name:	Last Name:		MI:	Phone Number:	
Address:	City:		State:	Zip Code:	
Date of Birth:	☐ Male ☐ Female	Circle unit of measure Height (in/cm): _____ Weight (lb/kg):_____		Allergies:	
Patient's Authorized Representative (if applicable):			Authorized Representative Phone Number:		

Insurance Information	
Primary Insurance Name:	Patient ID Number:
Secondary Insurance Name:	Patient ID Number:

Prescriber Information			
First Name:	Last Name:	Specialty:	
Address:	City:	State:	Zip Code:
Requestor (if different than prescriber):		Office Contact Person:	
NPI Number (individual):		Phone Number:	
DEA Number (if required):		Fax Number (in HIPAA compliant area):	
Email Address:			

Medication / Medical and Dispensing Information

Medication Name:

☐ New Therapy ☐ Renewal ☐ Step Therapy Exception Request
If Renewal: Date Therapy Initiated: Duration of Therapy (specific dates):

How did the patient receive the medication?
☐ Paid under Insurance Name:_____ Prior Auth Number (if known):_____
☐ Other (explain):

Dose/Strength:	Frequency:	Length of Therapy/#Refills:	Quantity:

Administration:
☐ Oral/SL ☐ Topical ☐ Injection ☐ IV ☐ Other:

Administration Location:
☐ Patient's Home ☐ Long Term Care
☐ Physician's Office ☐ Home Care Agency ☐ Other (explain):_____
☐ Ambulatory Infusion Center ☐ Outpatient Hospital Care _____

PRESCRIPTION DRUG PRIOR AUTHORIZATION OR STEP THERAPY EXCEPTION REQUEST FORM

Patient Name:	ID#:

Instructions: Please fill out all applicable sections on both pages completely and legibly. Attach any additional documentation that is important for the review, e.g. chart notes or lab data, to support the prior authorization or step therapy exception request.

1. Has the patient tried any other medications for this condition? ☐ **YES (if yes, complete below)** ☐ **NO**

Medication/Therapy (Specify Drug Name and Dosage)	**Duration of Therapy** (Specify Dates)	**Response/Reason for Failure/Allergy**

2. List Diagnoses:	**ICD-10:**

3. <u>Required clinical information</u> - Please provide all relevant clinical information to support a prior authorization or step therapy exception request review.

Please provide symptoms, lab results with dates and/or justification for initial or ongoing therapy or increased dose and if patient has any contraindications for the health plan/insurer preferred drug. Lab results with dates must be provided if needed to establish diagnosis, or evaluate response. Please provide any additional clinical information or comments pertinent to this request for coverage, including information related to exigent circumstances, or required under state and federal laws.

☐ Attachments

Attestation: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan, insurer, Medical Group or its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature or Electronic I.D. Verification:_____ **Date**:_____

Confidentiality Notice: The documents accompanying this transmission contain confidential health information that is legally privileged. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of these documents is strictly prohibited. If you have received this information in error, please notify the sender immediately (via return FAX) and arrange for the return or destruction of these documents.

Plan/Insurer Use Only: Date/Time Request Received by Plan/Insurer:_____ Date/Time of Decision_____

Fax Number (_____)_____

☐ Approved ☐ Denied Comments/Information Requested: _____

Kern Family Health Care™

NOTICE OF ACTION
About Your Treatment Request - Deny

Date

Member name
Address
City, State, Zip

Treating Provider
Address
City, State, Zip

Identification Number: KHS ID

RE: [Service requested]

[Name of requesting provider] has asked Kern Family Health Care to approve [Service requested].This request is denied. This is because [Insert: 1. A clear and concise explanation of the reasons for the decision; 2. A description of the criteria or guidelines used, including a reference to the specific regulations or plan authorization procedures that support the action; and. 3. The clinical reasons for the decision regarding medical necessity].

You can get free copies of all the information used to make this decision. To ask for this, please call Kern Family Health Care at **(661) 632-1590** inside Bakersfield, or **(800) 391-2000** outside of Bakersfield.

You can appeal this decision. The enclosed "Your Rights" information letter tells you how. It also tells you how you can get free help. This can be free legal help. You can send in any information that could help your case. The "Your Rights" letter tells you the last day you can ask for an appeal.

The State Medi-Cal Managed Care "Ombudsman Office" can help you with any questions. You may call them at 1-888-452-8609. You can also get help from your doctor, or call us at **(661) 632-1590** inside Bakersfield, or **(800) 391-2000** outside of Bakersfield.

This letter does not change your other Medi-Cal care.

Medical Directors Name

Enclosed: "Your Rights under Medi-Cal Managed Care"

YOUR RIGHTS
UNDER MEDI-CAL MANAGED CARE

IF YOU DO NOT AGREE WITH THE DECISION YOUR HEALTH PLAN MADE FOR YOUR HEALTH CARE, YOU CAN ASK YOUR HEALTH PLAN FOR AN APPEAL.

HOW DO I ASK FOR AN APPEAL?

You have 60 days from the date of this Notice of Action letter to ask for an appeal. If your health plan decided to reduce, suspend or terminate a service(s) you are getting now, you may be able to keep getting the service(s) until your appeal is decided. This is called Aid Paid Pending. To qualify for Aid Paid Pending, you must ask your health plan for an appeal within 10 days from the date of this Notice of Action letter, or before the date your health plan says the change to your service(s) will happen. Even though your health plan must give you Aid Paid Pending when you ask for an appeal within these timelines above, you should let your health plan know when you ask for an appeal that you want to get Aid Paid Pending until your appeal is decided.

If you miss the 10-day period to request an appeal OR do not ask for an appeal before the date the change to your service(s) will happen, you still have 60 days from the date of this Notice of Action letter to ask for an appeal. However, you will not get Aid Paid Pending while your appeal is being decided.

You can ask for an appeal yourself. Or, you can have someone like a relative, friend, advocate, doctor, or attorney to ask for one for you. This person is called an Authorized Representative. Your health plan can provide a form for you to identify your Authorized Representative. You, or your Authorized Representative, can send in anything you want your health plan to look at to make a decision on your appeal. A doctor who is different from the doctor who made the first decision will look at your appeal.

You can file an appeal by phone, in writing, or electronically:

- By phone: Contact Kern Family Health Care between 8:00 a.m. to 5:00 p.m. by calling **(661) 632-1590** inside Bakersfield, or **1-800-391-2000** outside Bakersfield. If you cannot hear or speak well, please call **711**.

- In writing: Fill out an appeal form or write a letter and send it to:

  Kern Family Health Care
  2900 Buck Owens Boulevard
  Bakersfield, CA. 93308

  Your doctor's office will have appeal forms available. Your health plan can also send a form to you.

- Electronically: Visit your health plan's website. Go to **https://www.kernfamilyhealthcare.com**

WHEN WILL MY APPEAL BE DECIDED?

For Standard Appeals, your health plan must respond to your appeal in writing within 30 days. If you think waiting 30 days will hurt your health, you may be able to get a decision in 72 hours. When you ask for an appeal with your health plan, say why waiting will hurt your health. Make sure you ask for an Expedited Appeal.

For Expedited Appeals, your health plan must try to give you an oral notice of its decision on your appeal. For both Standard and Expedited appeals, your health plan will mail you a Notice of Appeal Resolution letter. This letter will tell you what your health plan decided on your appeal.

CAN I ASK FOR AN INDEPENDENT MEDICAL REVIEW AND A STATE HEARING?

An Independent Medical Review is where a doctor(s) that is not related to the health plan will review your case. A State Hearing is where a judge will review your case.

If you disagree with your health plan's decision regarding your service(s), you can ask your health plan for an appeal. If you still disagree with your health plan's decision on your appeal, or it has been at least 30 days since you filed your appeal with your health plan, you can request an Independent Medical Review with the Department of Managed Health Care (DMHC). DMHC staff will determine whether your issue qualifies for an Independent Medical Review.

In most instances, you are not eligible to request a State Hearing until you have first completed your health plan's internal appeal process. However, there are times when you can directly request a State Hearing. This can happen if your health plan did not notify you correctly or timely about your service(s). This is called Deemed Exhaustion. Here are some examples of Deemed Exhaustion:

- The health plan did not make this Notice of Action letter available to you in your preferred language.
- The health plan made a mistake that affects any of your rights.
- The health plan did not give you a written Notice of Action letter informing you of its intended action regarding your service(s).
- The health plan made a mistake in its written Notice of Appeal Resolution letter.
- The health plan did not decide your appeal within 30 days and send you a Notice of Appeal Resolution letter.
- The health plan decided your case was urgent, but did not respond to your appeal within 72 hours and send you a Notice of Appeal Resolution letter.

Sometimes, you can ask for both an Independent Medical Review and a State Hearing at the same time. You can also ask for one before the other to see if one will resolve your problem first. For example, if you ask for an Independent Medical Review first, and you do not agree with what was decided, you can ask for a State Hearing. But, if you

ask for a State Hearing first, and your hearing has already taken place, you cannot ask for an Independent Medical Review. In this case, the State Hearing has the final say.

You will not have to pay for an Independent Medical Review or a State Hearing.

HOW DO I REQUEST AN INDEPENDENT MEDICAL REVIEW?

The paragraph below provides you with information on how to request an Independent Medical Review with DMHC.[1] Note that the term grievance is talking about both complaints and appeals:

"The California Department of Managed Health Care is responsible for regulating health care service plans. If you have a grievance against your health plan, you should first telephone your health plan at **1-800-391-2000** and use your health plan's grievance process before contacting the department. Utilizing this grievance procedure does not prohibit any potential legal rights or remedies that may be available to you. If you need help with a grievance involving an emergency, a grievance that has not been satisfactorily resolved by your health plan, or a grievance that has remained unresolved for more than 30 days, you may call the department for assistance. You may also be eligible for an Independent Medical Review (IMR). If you are eligible for IMR, the IMR process will provide an impartial review of medical decisions made by a health plan related to the medical necessity of a proposed service or treatment, coverage decisions for treatments that are experimental or investigational in nature and payment disputes for emergency or urgent medical services. The department also has a toll-free telephone number **(1-888-466-2219)** and a TDD line **(1-877-688-9891)** for the hearing and speech impaired. The department's internet website **www.dmhc.ca.gov** has complaint forms, IMR application forms, and instructions online."

HOW DO I REQUEST A STATE HEARING?

As stated above, you may be eligible to request a State Hearing.

You can ask for a State Hearing in the following ways:

- Online at www.cdss.ca.gov
- By phone: Call 1-800-743-8525. This number can be very busy. You may get a message to call back later. If you cannot speak or hear well, please call TTY/TDD 1-800-952-8349.
- In writing: Fill out a State Hearing form or write a letter. Send it by mail or fax to:

  Mail: California Department of Social Services

[1] Health and Safety Code (HSC) Section 1368.02(b). HSC is searchable at: http://leginfo.legislature.ca.gov/faces/home.xhtml.

State Hearings Division
P.O. Box 944243, Mail Station 9-17-37
Sacramento, CA 94244-2430

Fax: (916) 309-3487 or toll-free at 1-833-281-0903

A State Hearing Form is included with this letter. Be sure to include your name, address, telephone number, Social Security Number and/or CIN number, and the reason you want a State Hearing. If someone is helping you ask for a State Hearing, add their name, address, and telephone number to the form or letter. If you need an interpreter, tell the State Hearings Division what language you speak. You will not have to pay for an interpreter. The State Hearings Division will get you one. If you have a disability, the State Hearings Division can get you special accommodations free of charge to help you participate in the hearing. Please include information about your disability and the accommodation you need.

After you ask for a State Hearing, it could take up to 90 days to decide your case and send you an answer. If you think that waiting 90 days will hurt your health, you can request an Expedited Hearing. If the State Hearings Division approves your request for an Expedited Hearing, you may be able to get a hearing decision within 3 days from the date it receives your case file from your health plan.

You can ask for an Expedited Hearing by calling the State Hearings Division at the number above. Or, you can send the State Hearing form or a letter to the State Hearings Division. You must explain how waiting for up to 90 days for a decision will harm your life, health or ability to get or keep maximum function. You can also get a letter from your doctor to help show why you need an Expedited Hearing.

You can speak for yourself at the State Hearing. Or, you can have someone like a relative, friend, advocate, doctor, or attorney speak for you. If you want someone else to speak for you, then you must sign a form telling the State Hearings Division that the person can speak for you. This person is called an Authorized Representative.

LEGAL HELP

You may be able to get free legal help. Call the Greater Bakersfield Legal Assistance at (661) 325-5943. You may also call the local Legal Aid Office in your county at 1-888-804-3536.

Kern Family Health Care™

NONDISCRIMINATION NOTICE

Discrimination is against the law. Kern Family Health Care follows State and Federal civil rights laws. Kern Family Health Care does not unlawfully discriminate, exclude people, or treat them differently because of sex, race, color, religion, ancestry, national origin, ethnic group identification, age, mental disability, physical disability, medical condition, genetic information, marital status, gender, gender identity, or sexual orientation.

Kern Family Health Care provides:

- Free aids and services to people with disabilities to help them communicate better, such as:
  - ✓ Qualified sign language interpreters
  - ✓ Written information in other formats (large print, audio, accessible electronic formats, other formats)

- Free language services to people whose primary language is not English, such as:
  - ✓ Qualified interpreters
  - ✓ Information written in other languages

If you need these services, contact Kern Family Health Care at 1-800-391-200 between 8:00am – 5:00pm, Monday through Friday. If you cannot hear or speak well, please call the California Relay Service at 711. Upon request, this document can be made available to you in braille, large print, audiocassette, or electronic form. To obtain a copy in one of these alternative formats, please call or write to:

Kern Family Health Care
2900 Buck Owens Boulevard
Bakersfield, CA 93308
1-800-391-2000
711 (**California Relay Service**)

HOW TO FILE A GRIEVANCE

If you believe that Kern Family Health Care has failed to provide these services or unlawfully discriminated in another way on the basis of sex, race, color, religion, ancestry, national origin, ethnic group identification, age, mental disability, physical disability, medical condition, genetic information, marital status, gender, gender identity, or sexual orientation, you can file a grievance with Kern Family Health Care's Discrimination Grievance Coordinator. You can file a grievance by phone, in writing, in person, or electronically:

- By phone: Contact Kern Family Health Care's Discrimination Grievance Coordinator between 8:00am – 5:00pm, Monday through Friday by calling 1-800-391-2000. Or, if you cannot hear or speak well, please call the California Relay Service at 711.

- In writing: Fill out a complaint form or write a letter and send it to:

  Discrimination Grievance Coordinator
  Kern Family Health Care
  2900 Buck Owens Boulevard
  Bakersfield, CA 93308

- In person: Visit your doctor's office or Kern Family Health Care and say you want to file a grievance.

- Electronically: Visit Kern Family Health Care's website at www.kernfamilyhealthcare.com.

OFFICE OF CIVIL RIGHTS – CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES

You can also file a civil rights complaint with the California Department of Health Care Services, Office of Civil Rights by phone, in writing, or electronically:

- By phone: Call **916-440-7370**. If you cannot speak or hear well, please call **711 (California Relay Service)**.

- In writing: Fill out a complaint form or send a letter to:

  Deputy Director, Office of Civil Rights
  Department of Health Care Services
  Office of Civil Rights
  P.O. Box 997413, MS 0009
  Sacramento, CA 95899-7413

  Complaint forms are available at http://www.dhcs.ca.gov/Pages/Language_Access.aspx.

- Electronically: Send an email to CivilRights@dhcs.ca.gov.

OFFICE OF CIVIL RIGHTS – U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

If you believe you have been discriminated against on the basis of race, color, national origin, age, disability or sex, you can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights by phone, in writing, or electronically:

- By phone: Call **1-800-368-1019**. If you cannot speak or hear well, please call **TTY/TDD 1-800-537-7697**.

- In writing: Fill out a complaint form or send a letter to:

  U.S. Department of Health and Human Services
  200 Independence Avenue, SW
  Room 509F, HHH Building
  Washington, D.C. 20201

  Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

- Electronically: Visit the Office for Civil Rights Complaint Portal at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf.

HOW TO FILE A GRIEVANCE

If you believe that Kern Family Health Care has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with Kern Family Health Care. You can file a grievance by phone, in writing, in person, or electronically:

- By phone: Contact Kern Family Health Care between 8:00 a.m. to 5:00 p.m. by calling (661) 632-1590 inside Bakersfield, or 1-800-391-2000 outside Bakersfield. Or, if you cannot hear or speak well, please call 711.
-
- In writing: Fill out a complaint form or write a letter and send it to:

  Kern Family Health Care
  2900 Buck Owens Boulevard
  Bakersfield, CA 93308

- In person: Visit your doctor's office or Kern Family Health Care and say you want to file a grievance.

- Electronically: Visit Kern Family Health Care's website at http://www.kernfamilyhealthcare.com/.

OFFICE OF CIVIL RIGHTS

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights by phone, in writing, or electronically:

- By phone: Call **1-800-368-1019**. If you cannot speak or hear well, please call **TTY/TDD 1-800-537-7697**.

- In writing: Fill out a complaint form or send a letter to:

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  Washington, D.C. 20201

  Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

- Electronically: Visit the Office for Civil Rights Complaint Portal at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf.

Kern Family Health Care

TAGLINES

English Tagline

ATTENTION: If you need help in your language call 1-800-391-2000 (TTY: 711). Aids and services for people with disabilities, like documents in braille and large print, are also available. Call 1-800-391-2000 (TTY: 711). These services are free of charge.

الشعار بالعربية (Arabic)

يُرجى الانتباه: إذا احتجت إلى المساعدة بلغتك، فاتصل بـ 1-800-391-2000 (TTY: 711). تتوفر أيضًا المساعدات والخدمات للأشخاص ذوي الإعاقة، مثل المستندات المكتوبة بطريقة بريل والخط الكبير. اتصل بـ 1-800-391-2000 (TTY: 711). هذه الخدمات مجانية.

Հայերեն պիտակ (Armenian)

ՈՒՇԱԴՐՈՒԹՅՈՒՆ: Եթե Ձեզ օգնություն է հարկավոր Ձեր լեզվով, զանգահարեք 1-800-391-2000 (TTY: 711): Կան նաև օժանդակ միջոցներ ու ծառայություններ հաշմանդամություն ունեցող անձանց համար, օրինակ՝ Բրայլի գրատիպով ու խոշորատառ տպագրված նյութեր: Զանգահարեք 1-800-391-2000 (TTY: 711): Այդ ծառայություններն անվճար են:

ឃ្លាសម្គាល់ជាភាសាខ្មែរ (Cambodian)

ចំណាំ៖ បើអ្នក ត្រូវ ការជំនួយ ជាភាសា របស់អ្នក សូម ទូរស័ព្ទទៅលេខ 1-800-391-2000 (TTY: 711)។ ជំនួយ និង សេវាកម្ម សម្រាប់ ជនពិការ ដូចជាឯកសារសរសេរជាអក្សរផុស សម្រាប់ជនពិការភ្នែក ឬឯកសារសរសេរជាអក្សរពុម្ពធំ ក៏អាចរកបានផងដែរ។ ទូរស័ព្ទមកលេខ 1-800-391-2000 (TTY: 711)។ សេវាកម្មទាំងនេះមិនគិតថ្លៃឡើយ។

简体中文标语 (Simplified Chinese)

请注意：如果您需要以您的母语提供帮助，请致电 1-800-391-2000 (TTY: 711)。我们另外还提供针对残疾人士的帮助和服务，例如盲文和大字体阅读，提供您方便取用。请致电 1-800-391-2000 (TTY: 711)。这些服务都是免费的。

مطلب به زبان فارسی (Farsi)

توجه: اگر می‌خواهید به زبان خود کمک دریافت کنید، با 1-800-391-2000 (TTY: 711) تماس بگیرید. کمک‌ها و خدمات مخصوص افراد دارای معلولیت، مانند نسخه‌های خط بریل و چاپ با حروف بزرگ، نیز موجود است. با 1-800-391-2000 (TTY: 711) تماس بگیرید. این خدمات رایگان ارائه می‌شوند.

हिंदी टैगलाइन (Hindi)
ध्यान दें: अगर आपको अपनी भाषा में सहायता की आवश्यकता है तो 1-800-391-2000 (TTY: 711) पर कॉल करें। अशक्तता वाले लोगों के लिए सहायता और सेवाएं, जैसे ब्रेल और बड़े प्रिंट में भी दस्तावेज़ उपलब्ध हैं। 1-800-391-2000 (TTY: 711) पर कॉल करें। ये सेवाएं नि: शुल्क हैं।

Nqe Lus Hmoob Cob (Hmong)
CEEB TOOM: Yog koj xav tau kev pab txhais koj hom lus hu rau 1-800-391-2000 (TTY: 711). Muaj cov kev pab txhawb thiab kev pab cuam rau cov neeg xiam oob qhab, xws li puav leej muaj ua cov ntawv su thiab luam tawm ua tus ntawv loj. Hu rau 1-800-391-2000 (TTY: 711). Cov kev pab cuam no yog pab dawb xwb.

日本語表記 (Japanese)
注意日本語での対応が必要な場合は 1-800-391-2000 (TTY: 711)へお電話ください。点字の資料や文字の拡大表示など、障がいをお持ちの方のためのサービスも用意しています。 1-800-391-2000 (TTY: 711)へお電話ください。これらのサービスは無料で提供しています。

한국어 태그라인 (Korean)
유의사항: 귀하의 언어로 도움을 받고 싶으시면 1-800-391-2000 (TTY: 711) 번으로 문의하십시오. 점자나 큰 활자로 된 문서와 같이 장애가 있는 분들을 위한 도움과 서비스도 이용 가능합니다. 1-800-391-2000 (TTY: 711) 번으로 문의하십시오. 이러한 서비스는 무료로 제공됩니다.

ແທກໄລພາສາລາວ (Laotian)
ປະກາດ: ຖ້າທ່ານຕ້ອງການຄວາມຊ່ວຍເຫຼືອໃນພາສາຂອງທ່ານໃຫ້ໂທຫາເບີ 1-800-391-2000 (TTY: 711). ຍັງມີຄວາມຊ່ວຍເຫຼືອແລະການບໍລິການສໍາລັບຄົນພິການ
ເຊັ່ນເອກະສານທີ່ເປັນອັກສອນນູນແລະມີໂຕພິມໃຫຍ່ ໃຫ້ໂທຫາເບີ
1-800-391-2000 (TTY: 711). ການບໍລິການເຫຼົ່ານີ້ບໍ່ຕ້ອງເສຍຄ່າໃຊ້ຈ່າຍໃດໆ.

Mien Tagline (Mien)
LONGC HNYOUV JANGX LONGX OC: Beiv taux meih qiemx longc mienh tengx faan benx meih nyei waac nor douc waac daaih lorx taux 1-800-391-2000 (TTY: 711). Liouh lorx jauv-louc tengx aengx caux nzie gong bun taux ninh mbuo wuaaic fangx mienh, beiv taux longc benx nzangc-pokc bun hluo mbiutc aengx caux aamz mborqv benx domh sou se mbenc nzoih bun longc. Douc waac daaih lorx 1-800-391-2000 (TTY: 711). Naaiv deix nzie weih gong-bou jauv-louc se benx wang-henh tengx mv zuqc cuotv nyaanh oc.

ਪੰਜਾਬੀ ਟੈਗਲਾਈਨ (Punjabi)
ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਹਾਨੂੰ ਆਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਮਦਦ ਦੀ ਲੋੜ ਹੈ ਤਾਂ ਕਾਲ ਕਰੋ 1-800-391-2000 (TTY: 711). ਅਪਾਹਜ ਲੋਕਾਂ ਲਈ ਸਹਾਇਤਾ ਅਤੇ ਸੇਵਾਵਾਂ, ਜਿਵੇਂ ਕਿ ਬ੍ਰੇਲ ਅਤੇ ਮੋਟੀ ਛਪਾਈ ਵਿੱਚ ਦਸਤਾਵੇਜ਼, ਵੀ ਉਪਲਬਧ ਹਨ| ਕਾਲ ਕਰੋ 1-800-391-2000 (TTY: 711). ਇਹ ਸੇਵਾਵਾਂ ਮੁਫਤ ਹਨ|

Русский слоган (Russian)

ВНИМАНИЕ! Если вам нужна помощь на вашем родном языке, звоните по номеру 1-800-391-2000 (линия TTY: 711). Также предоставляются средства и услуги для людей с ограниченными возможностями, например документы крупным шрифтом или шрифтом Брайля. Звоните по номеру 1-800-391-2000 (линия TTY: 711). Такие услуги предоставляются бесплатно.

Mensaje en español (Spanish)

ATENCIÓN: si necesita ayuda en su idioma, llame al 1-800-391-2000 (TTY: 711). También ofrecemos asistencia y servicios para personas con discapacidades, como documentos en braille y con letras grandes. Llame al 1-800-391-2000 (TTY: 711). Estos servicios son gratuitos.

Tagalog Tagline (Tagalog)

ATENSIYON: Kung kailangan mo ng tulong sa iyong wika, tumawag sa 1-800-391-2000 (TTY: 711). Mayroon ding mga tulong at serbisyo para sa mga taong may kapansanan,tulad ng mga dokumento sa braille at malaking print. Tumawag sa 1-800-391-2000 (TTY: 711). Libre ang mga serbisyong ito.

แท็กไลน์ภาษาไทย (Thai)

โปรดทราบ: หากคุณต้องการความช่วยเหลือเป็นภาษาของคุณ กรุณาโทรศัพท์ไปที่หมายเลข 1-800-391-2000 (TTY: 711) นอกจากนี้ ยังพร้อมให้ความช่วยเหลือและบริการต่าง ๆ สำหรับบุคคลที่มีความพิการ เช่น เอกสารต่าง ๆ ที่เป็นอักษรเบรลล์และเอกสารที่พิมพ์ด้วยตัวอักษรขนาดใหญ่ กรุณาโทรศัพท์ไปที่หมายเลข 1-800-391-2000 (TTY: 711) ไม่มีค่าใช้จ่ายสำหรับบริการเหล่านี้

Примітка українською (Ukrainian)

УВАГА! Якщо вам потрібна допомога вашою рідною мовою, телефонуйте на номер 1-800-391-2000 (TTY: 711). Люди з обмеженими можливостями також можуть скористатися допоміжними засобами та послугами, наприклад, отримати документи, надруковані шрифтом Брайля та великим шрифтом. Телефонуйте на номер 1-800-391-2000 (TTY: 711). Ці послуги безкоштовні.

Khẩu hiệu tiếng Việt (Vietnamese)

CHÚ Ý: Nếu quý vị cần trợ giúp bằng ngôn ngữ của mình, vui lòng gọi số 1-800-391-2000 (TTY: 711). Chúng tôi cũng hỗ trợ và cung cấp các dịch vụ dành cho người khuyết tật, như tài liệu bằng chữ nổi Braille và chữ khổ lớn (chữ hoa). Vui lòng gọi số 1-800-391-2000 (TTY: 711). Các dịch vụ này đều miễn phí.

U.S. Department of Health and Human Services

Form Approved: OMB No. 0910-0291, Expires: 03/31/05
See OMB statement on reverse.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

Page ____ of ____

FDA USE ONLY
Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier — In confidence
2. Age at Time of Event: or Date of Birth:
3. Sex: ☐ Female ☐ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
☐ Death: ____ (mo/day/yr)
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Disability
☐ Congenital Anomaly
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Other: ____

3. Date of Event (mo/day/year)

4. Date of This Report (mo/day/year)

5. Describe Event or Problem

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. SUSPECT MEDICATION(S)

1. Name (Give labeled strength & manufacturer, if known)
#1
#2

2. Dose, Frequency & Route Used
#1
#2

3. Therapy Dates (if unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot # (if known)
#1
#2

7. Exp. Date (if known)
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# (For product problems only)
- -

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Type of Device
3. Manufacturer Name, City and State
4. Model # | Lot # | 5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
Catalog # | Expiration Date (mo/day/yr)
Serial # | Other #
6. If Implanted, Give Date (mo/day/yr)
7. If Explanted, Give Date (mo/day/yr)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mo/day/yr)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. REPORTER (See confidentiality section on back)

1. Name and Address
Phone #

2. Health Professional? ☐ Yes ☐ No
3. Occupation
4. Also Reported to: ☐ Manufacturer ☐ User Facility ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FDA

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 -or- FAX to: 1-800-FDA-0178

FORM FDA 3500 (9/03) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:

- Medications *(drugs or biologics)*
- Medical devices *(including in-vitro diagnostics)*
- Special nutritional products *(dietary supplements, medical foods, infant formulas)*
- Cosmetics
- Medication errors

Report product problems - quality, performance or safety concerns such as:

- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening *(real risk of dying)*
- Hospitalization *(initial or prolonged)*
- Disability *(significant, persistent or permanent)*
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage

Report even if:

- You're not certain the product caused the event
- You don't have all the details

How to report:

- Just fill in the sections that apply to your report
- Use section C for all products except medical devices
- Attach additional blank pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer *(or both)*

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Important numbers:

- 1-800-FDA-0178 -- To FAX report
- 1-800-FDA-1088 -- To report by phone or for more information
- 1-800-822-7967 -- For a VAERS form for vaccines

To Report via the Internet:

http://www.fda.gov/medwatch/report.htm

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
MedWatch; HFD-410
5600 Fishers Lane
Rockville, MD 20857

Please DO NOT RETURN this form to this address.

OMB statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FORM FDA 3500 (9/03) (Back) **Please Use Address Provided Below -- Fold in Thirds, Tape and Mail**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787