Section 7. Medical Exceptions Approval Process Requirements and Procedures

A. Each health carrier that provides prescription drug benefits and manages this benefit through the use of a formulary or through the application of a dose restriction that causes a prescription for a particular drug not to be covered for the number of doses prescribed or step therapy requirement that causes a particular drug not be covered until the requirements of that PBMP have been met shall establish and maintain a medical exceptions process that allows covered persons or covered persons’ authorized representatives to request approval for:

(1) Coverage of a prescription drug that is not covered based on the health carrier’s formulary;

(2) Continued coverage of a particular prescription drug that the health carrier is discontinuing coverage on the formulary for reasons other than safety except when coverage for the drug is being discontinued because of safety reasons or because the drug’s manufacturer is no longer supplying the prescription drug cannot be supplied by or has been withdrawn from the market by the drug’s manufacturer has withdrawn the prescription drug from the market; or

(3) An exception to a PBMP that causes a prescription drug to not be covered until the step therapy requirement is satisfied or not be covered at the prescribed number of doses; or not be covered as the result of any other utilization management requirement that restricts coverage of the prescription drug.

Drafting Note: States should ensure that health benefit plans have a process in place to address issues that may not fall under this section as a formulary exception, but would be considered a benefit exception.

Drafting Note: This section is not intended to apply to requests for an exception to a pharmaceutical benefit management procedure (PBMP) involving a prior authorization requirement. Those types of requests for benefits for which a health carrier requires prior authorization are to be resolved under a health carrier’s utilization review process.

Drafting Note: This section also is not intended to apply to situations where the consumer may have issues with pharmacy access, such as an in-network pharmacy being too far from a covered person’s home address or when a prescription drug a covered person is currently using changes from being available through a range of pharmacy options to mail order pharmacy only. In these situations, states should review the network access requirements in state law or regulation similar to the requirements in the Health Benefit Plan Network Access and Adequacy Model Act (#74).

B. (1) A covered person or the covered person’s authorized representative may file and the carrier shall approve a request under Subsection A only if the covered person’s prescribing provider has determined that the requested prescription drug is medically necessary to treat the covered person’s disease or medical condition because:

(a) There is not a prescription drug listed on the formulary to treat the covered person’s disease or medical condition that is an acceptable clinical alternative;

(b) The prescription drug alternative listed on the formulary or required to be used in accordance with step therapy requirements:

(i) Has been ineffective in the treatment of the covered person’s disease or medical condition while under the current or previous health insurance or health benefit plan or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the covered person and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug’s effectiveness or patient compliance; or

(ii) Has is contraindicated or has caused or based on sound clinical evidence and medical and scientific evidence is likely to cause an adverse reaction or other harm to the covered person in the prescriber’s clinical judgment; or
(c) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the covered person’s disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the covered person and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug’s effectiveness or patient compliance; or

(d) The covered person has tried another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued by the prescriber due to lack of efficacy or effectiveness, diminished effect, or

(e) The covered person’s condition and function are stable on a prescription drug selected by their health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan and a change in prescription drug has the potential for adverse consequences or other risks.

(2) (a) A health carrier may require the covered person or the covered person’s authorized representative upon request to provide a written certification from the covered person’s prescribing provider of the determination made under Paragraph (1).

(b) The health carrier may require the written certification to include any of, but no more than, the following information:

(i) The patient’s name, group or contract number, subscriber number or other information necessary to identify the covered person; (ii) Patient history; (iii) The primary diagnosis related to the requested prescription drug that is the subject of the medical exceptions request; (iv) Based on Paragraph (1)(a), (b) or (c), the reason: (I) Why the formulary drug is not acceptable for the individual patient; (II) If the medical exceptions request involves a step therapy requirement, why the prescription drug required to be used is not acceptable for the individual patient; or (III) If the medical exceptions request involves a dose restriction, why the available number of doses for the prescription drug is not acceptable for the individual patient; (v) The reason why the prescription drug that is the subject of the medical exceptions request is needed for the individual patient or, if the medical exceptions request involves a dose restriction, why an exception to the dose restriction is needed for the individual patient; and (vi) Any other information reasonably necessary to evaluate the medical necessity of the medical exceptions request.

(3) Participation by a provider on behalf of a covered person in the medical exceptions process established under this section shall be construed as being the same as a provider’s advocating on behalf of a covered person within the utilization review process established by the health carrier for purposes of [insert reference to state law equivalent to Section 6J of the Managed Care Plan Network Adequacy Model Act].

Drafting Note: Section 6J of the NAIC Managed Care Plan Network Adequacy Model Act provides that a health carrier may not prohibit a participating provider from advocating on behalf of a covered person within the utilization review or grievance processes established by the carrier or a person contracting with the carrier. The medical exceptions process established under this section for the review of requests for approval for exceptions to a formulary or being subject to a dose restriction or step therapy requirement is similar to the expedited utilization review process that health carriers may be required to establish for the review of health care service benefit requests. Paragraph (3) is intended to ensure that providers participating in the medical exceptions process established under this section have the same protections given to participating providers under Section 6J of the NAIC Managed Care Plan Network Adequacy Model Act.

C. (1) Upon receipt of a request made pursuant to Subsection A, the health carrier shall ensure that the request is reviewed by appropriate health care professionals who, in reaching a decision on the request, shall take into account the specific facts and circumstances that apply to the covered person for whom the request has been made using documented clinical review criteria that:

(a) Are based on sound clinical evidence and medical and scientific evidence; and

(b) If available, appropriate practice guidelines, which may include generally accepted practice guidelines, evidence-based practice guidelines, practice guidelines developed by the health carrier’s P&T committee or any other practice guidelines developed by the federal government, national or professional medical or pharmacist societies, boards and associations.
D. (1) (a) Except as provided in Subparagraph (b) of this paragraph, if the health carrier makes a decision on a request made pursuant to Subsection A, the health carrier shall provide notice of the decision to the covered person or the covered person’s authorized representative as quickly as the covered person’s particular medical condition requires, but in no event later than seventy-two (72) hours after the later of the date of receipt of the request or, if required by the health carrier, the date of receipt of the certification under Subsection B(2).

(b) (i) A health carrier shall include in its medical exceptions process required under Subsection A an expedited medical exceptions review based on exigent circumstances.

(ii) Exigent circumstances exist when a covered person is suffering from a health condition that may seriously jeopardize the covered person’s life, health, or ability to regain maximum function.

(iii) A health carrier shall make a decision on an expedited medical exceptions review request based on exigent circumstances made pursuant to Subsection A and notify the covered person or the covered person’s authorized representative of its coverage decision no later than 24 hours following receipt of the request.

(2) (a) If the health carrier fails to make a decision on the request and provide notice of the decision within the time frame required under Paragraph (1)(a) or Paragraph (1)(b): (i) The covered person shall be entitled to have coverage for, up to one month’s supply of the prescription drug that is the subject of the request; and (ii) The health carrier shall make a decision on the request prior to the covered person’s completion of the supply provided in Item (i).

(b) If the health carrier fails to make a decision on the request and provide notice of the decision prior to the covered person’s completion of the supply provided for in Subparagraph (a) of this paragraph, the health carrier shall maintain coverage, as specified in Subparagraph (a) of this paragraph, on the same terms on an ongoing basis, as long as the prescription drug continues to be prescribed for that covered person and is considered safe for the treatment of the covered person’s disease or medical condition until a decision is made on the request and notice of that decision is provided, unless there is a material change in the covered person’s terms of coverage or the applicable benefit limits have been exhausted.

E. (1) Whenever a request made under this section is approved, the health carrier shall not require the covered person to request approval under this section for a refill, or a new prescription to continue using the prescription drug after the refills for the initial prescription have been exhausted, for the same prescription drug that was previously approved under this section for coverage or continued coverage or that was previously approved under this section as an exception to the health carrier’s PBMP for that drug, subject to the terms of coverage under the health carrier’s health benefit plan for prescription drug benefits as long as:
(a) The covered person’s prescribing provider continues to prescribe the prescription drug to treat the same disease or medical condition of the covered person; and
(b) The prescription drug continues to be considered safe for treating the covered person’s disease or medical condition.

(2) In addition to Paragraph (1), whenever a request made under this section is approved, the health carrier shall provide coverage for the approved prescription drug.

(3) A health carrier shall not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

Drafting Note: A state that requires health carriers to establish specific formulary tiers with specific cost-sharing requirements for each tier should modify the language in Paragraph (3) to take into account the requirements of its law.

F. (1) Any denial by a health carrier of a request made under Subsection A:
(a) Shall be provided to the covered person or, if applicable, the covered person’s authorized representative in writing or, if the covered person has agreed to receive information in this manner, electronically;
(b) Shall be provided electronically to the covered person’s prescribing provider or, upon request, in writing; and
(c) May be appealed by filing a grievance pursuant to [insert reference in state law equivalent to the Health Carrier Grievance Procedure Model Act].

(2) The denial shall, in a manner calculated to be understood by the covered person or, if applicable, the covered person’s authorized representative, set forth:
(a) The specific reason or reasons for the denial;
(b) A reference to the evidence or documentation, including the clinical review criteria, including practice guidelines, and clinical evidence and medical and scientific evidence considered in reaching the decision to deny the request;
(c) Instructions for requesting, a written statement of the clinical and medical or scientific rationale for the denial; and
(d) A description of the process and procedures that must be followed for filing a grievance to appeal the denial pursuant to [insert reference in state law equivalent to the Health Carrier Grievance Procedure Model Act], including any time limits applicable to those procedures.

G. A health carrier that permits a covered person’s prescribing participating provider to make formulary and other PBMP exceptions without having to obtain authorization from the carrier and that maintains on an ongoing basis in its administrative systems information about the exception status of a particular prescription drug for a particular covered person shall not be required to establish a medical exceptions process in accordance with Subsection A or required to comply with the provisions of Subsections B, C, D, E(1) and (2) and F with respect to the prescription drug orders of these prescribing participating providers.

H. A health carrier shall not be required to establish a medical exceptions process in accordance with Subsection A or required to comply with the provisions of Subsections B, C, D, E(1) and (2) and F if the health carrier:

(1) Has an expedited utilization review process as set forth in [insert reference in state law equivalent to Section 10 of the Utilization Review and Benefit Determination Model Act]; and

(2) Allows covered persons or their authorized representatives to use this process to seek approval for coverage of a prescription drug that is not otherwise covered because of the health carrier’s formulary or because of any other PBMP requirement that restricts coverage of the prescription drug until the PBMP requirement has been met.

I. Nothing in this section shall be construed to allow a covered person to use the medical exceptions process set out in this section to request coverage for a prescription drug that is categorically or contractually excluded from coverage under the covered person’s health benefit plan.