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TRICARE
MANAGEMENT
ACTIVITY

August 6, 2009

MEMORANDUM FOR PHARMACY AND THERAPEUTICS COMMITTEE

SUBJECT: Implementation of Final Rule on Federal Ceiling Prices

A. Background.

As you know, the Final Rule implementing the Federal Ceiling Prices statute for the Retail Pharmacy Network became effective May 26, 2009 (copy of new regulation provisions attached; complete Final Rule with preamble available at: http://www.tricare.mil/pharm_mfg/default.cfm).

The Final Rule includes a new requirement for Tier 2 of the Uniform Formulary. 21 C.F.R. § 199.21(q)(2) provides that a "written agreement by a manufacturer to honor" Federal Ceiling Prices "for pharmaceuticals provided through retail network pharmacies shall with respect to a particular covered drug be a condition for: (A) Inclusion of that drug on" Tier 2; "and (B) Availability of that drug through retail network pharmacies without preauthorization."

Whereas the old rule was that a UF-VARR was *considered* by the P&T Committee as part of the judgment of "cost-effectiveness," the new rule is that a UF-VARR or a pricing agreement at FCP or below is *required* for the drug to be eligible for Tier 2. In other words, a drug cannot be considered cost-effective by the P&T Committee for purposes of Tier 2 if it fails to at least comply with the maximum price allowed by law. Companies that sign a pricing agreement are agreeing to give DoD a price of at least 24% less that the Non-Federal Average Manufacturers Price in the retail venue compared to those in the same class that do not. Further, whereas the old rule was that Tier 3 drugs remained available at retail pharmacies, the new rule is that Tier 3 drugs not covered by pricing agreements will only be available at TMOP, unless preauthorized for retail dispensing.

B. Transition Provisions.

Recognizing that this is a significant program change, the Final Rule provides for a smooth transition, particularly to protect beneficiaries from any undue inconvenience. The following flexibilities are available:

1. *Effective date.* Most important is to give pharmaceutical companies some time to understand the new requirements and come into compliance. Already, in less than two and one-half months, as measured by dollar value, 91% of the TRICARE retail market is under

pricing agreements at FCP or below. Noncompliant companies can be given additional time to preserve Tier 2 eligibility by signing an agreement.

2. *MTF availability.* The Final Rule (in paragraph (q)(5)) permits continued availability at MTF pharmacies of any noncompliant drugs moved to Tier 3. MTF availability may continue as if the drug were still on Tier 2.

3. *Retail preauthorization.* The Final Rule (also in paragraph (q)(5)) additionally allows any noncompliant drug moved to Tier 3 to continue to be dispensed at retail as if it were still on Tier 2 for a transitional time period. This will give beneficiaries time to arrange for TMOP dispensing (where Tier 3 copays are still less than Tier 2 retail copays) or consider switching to a clinically equivalent Tier 1 or Tier 2 alternative.

4. *Clinical necessity.* In addition to any temporary transition provisions, as under current practice, a clinical necessity determination can always permit a Tier 3 drug to be dispensed at a Tier 2 copay, including in the retail network. This may be appropriate for certain patents with particular clinical conditions.

5. *Tier 2 waiver.* The Final Rule (in paragraph (q)(2)(iv)) authorizes exceptions to the rule requiring a pricing agreement at or below FCP as a precondition for Tier 2 eligibility if necessary to ensure that at least one drug in the drug class remains on Tier 2. The P&T Committee may continue to exercise professional judgment in defining drug classes and subclasses to ensure responsiveness to patient needs.

6. *Deferred evaluation.* Finally, if there are special circumstances with regard to a particular drug, the P&T Committee may defer a recommendation with respect to Uniform Formulary Tier placement of that drug until the next quarterly meeting, and may ask the PEC for input regarding the special circumstances for consideration at that meeting.

C. <u>Recommended approach</u>.

In order to both implement the Final Rule's new requirements and ensure a smooth transition, the Pharmacy Operations Directorate recommends the following approach for the P&T Committee at the August meeting:

1. *Tier 3 status and effective date.* Except as provided in paragraph C.4 or C.5 below, all drugs not covered by a pricing agreement or UF-VARR at FCP or below are recommended for Tier 3 status (the list of such drugs to be attached to the P&T Committee recommendations), with the following provisos:

a. The effective date will not be before January 1, 2010.

b. If prior to November 1, 2009, the drug comes under such a pricing agreement (effective for prescriptions filled on or after May 26, 2009), the move to

Tier 3 should not be implemented. (This would be reflected in the TMA Director's approval of the minutes.)

c. The November meeting of the P&T Committee will be updated on the status of pricing agreements for these drugs and have the opportunity to recommend any changes to the August meeting recommendations if new special circumstances are determined to exist.

2. *MTF availability.* During 2010, the move to Tier 3 of non-complying drugs will not affect MTF availability.

3. *Retail preauthorization.* Following the move to Tier 3 of any non-complying drug, beneficiaries will be given at least 90 days (during which time Tier 2 copays can be maintained) to understand their options and make an appropriate choice before preauthorization for retail dispensing of the drug would be required. The Pharmacy Benefits Manager contractor will contact the beneficiary, provide information on options, and offer assistance in obtaining future prescriptions through TMOP or switching to a Tier 1 or Tier 2 alternative.

4. *Clinical necessity.* Identify any particular drugs and/or particular circumstances where criteria should be developed to approve clinical necessity determinations to permit a Tier 3 drug to be dispensed at a Tier 2 copay in the retail network.

5. *Tier 2 waiver.* List any drugs the P&T Committee determines should be exempted from the requirement for a pricing agreement in order to ensure that at least one drug in the drug class remains on Tier 2.

6. *Deferred evaluation.* List any drugs the P&T Committee determines should be deferred to the next meeting of the P&T Committee to consider special circumstances and identify any information needs to be filled for that consideration.

D. <u>Conclusion</u>.

Implementation of the Final Rule is a major milestone in the history of the TRICARE Pharmacy Benefits Program. The leadership and clinical expertise of the P&T Committee are vital to this process and greatly appreciated.

Thomas J. McGinnis
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Chief, Pharmaceutical Operations Directorate

Attachment (a/s)

Attachment: Copy of new regulation provisions; complete Final Rule with preamble is available at: http://www.tricare.mil/pharm_mfg/default.cfm).

Sec. 199.21. Pharmacy Benefits Program.

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(q) Pricing standards for retail pharmacy program.

(1) Statutory requirement.

(i) As required by 10 U.S.C. § 1074g(f), with respect to any prescription filled on or after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2008, the TRICARE retail pharmacy program shall be treated as an element of the DoD for purposes of the procurement of drugs by Federal agencies under 38 U.S.C. § 8126 to the extent necessary to ensure pharmaceuticals paid for by the DoD that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards in such section 8126.

(ii) Under subparagraph (q)(1)(i) of this section, all covered drug TRICARE retail pharmacy network prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. § 8126.

(2) Manufacturer written agreement.

(i) A written agreement by a manufacturer to honor the pricing standards required by 10 U.S.C. § 1074g(f) and referred to in paragraph (q)(1) of this section for pharmaceuticals provided through retail network pharmacies shall with respect to a particular covered drug be a condition for:

(A) Inclusion of that drug on the uniform formulary under this section; and

(B) Availability of that drug through retail network pharmacies without preauthorization under paragraph (k) of this section.

(ii) A covered drug not under an agreement under paragraph (q)(2)(i) of this section requires preauthorization under paragraph (k) of this section to be provided through a retail network pharmacy under the Pharmacy Benefits Program. This preauthorization requirement does not apply to other points of service under the Pharmacy Benefits Program.

(iii) For purposes of this paragraph (q)(2), a covered drug is a drug that is a covered drug under 38 U.S.C. § 8126, but does not include:

(A) A drug that is not a covered drug under 38 U.S.C. 8126;

(B) A drug provided under a prescription that is not covered by 10 U.S.C. 1074g(f);

(C) A drug that is not provided through a retail network pharmacy under this section;

(D) A drug provided under a prescription which the TRICARE Pharmacy Benefits Program is the second payer under paragraph (m) of this section;

(E) A drug provided under a prescription and dispensed by a pharmacy under section 340B of the Public Health Service Act; or

(F) Any other exception for a drug, consistent with law, established by the Director, TMA.

(iv) The requirement of this paragraph (q)(2) may, upon the recommendation of the Pharmacy and Therapeutics Committee, be waived by the Director, TMA if necessary to ensure that at least one drug in the drug class is included on the Uniform Formulary. Any such waiver, however, does not waive the statutory requirement referred to in paragraph (q)(1) that all covered TRICARE retail network pharmacy prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. § 8126; it only waives the exclusion from the Uniform Formulary of drugs not covered by agreements under this paragraph (q)(2).

(3) Refund procedures.

(i) Refund procedures to ensure that pharmaceuticals paid for by the DoD that are provided by retail network pharmacies under the pharmacy benefits program are subject to the pricing standards referred to in paragraph (q)(1) of this section shall be established. Such procedures may be established as part of the agreement referred to in paragraph (q)(2), or in a separate agreement, or pursuant to section 199.11.

(ii) The refund procedures referred to in paragraph (q)(3)(i) of this section shall, to the extent practicable, incorporate common industry practices for implementing pricing agreements between manufacturers and large pharmacy benefit plan sponsors. Such procedures shall provide the manufacturer at least 70 days from the date of the submission of the TRICARE pharmaceutical utilization data needed to calculate the refund before the refund payment is due. The basis of the refund will be the difference between the average non-federal price of the drug sold by the manufacturer to wholesalers, as represented by the most recent annual non-Federal average manufacturing prices (non-FAMP) (reported to the Department of Veterans Affairs (VA)) and the corresponding FCP or, in the discretion of the manufacturer, the difference between the FCP and direct commercial contract sales prices specifically attributable to the reported TRICARE paid pharmaceuticals, determined for each applicable NDC listing. The current annual FCP and the annual non-FAMP from which it was derived will be applicable to all prescriptions filled during the calendar year.

(iii) A refund due under this paragraph (q) is subject to section 199.11 of this part and will be treated as an erroneous payment under that section.

(A) A manufacturer may under section 199.11 of this part request waiver or compromise of a refund amount due under 10 U.S.C. § 1074g(f) and this paragraph (q).

(B) During the pendency of any request for waiver or compromise under subparagraph (q)(3)(iii)(A) of this section, a manufacturer's written agreement under paragraph (q)(2) shall be deemed to exclude the matter that is the subject of the request for waiver or compromise. In such cases the agreement, if otherwise sufficient for the purpose of the condition referred to in paragraph (q)(2), will continue to be sufficient for that purpose. Further, during the pendency of any such request, the matter that is the subject of the request shall not be considered a failure of a manufacturer to honor an agreement for purposes of paragraph (q)(4).

(C) In addition to the criteria established in section 199.11 of this section, a request for waiver may also be premised on the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program.

(iv) In the case of disputes by the manufacturer of the accuracy of TMA's utilization data, a refund obligation as to the amount in dispute will be deferred pending good faith efforts to resolve the dispute in accordance with procedures established by the Director, TMA. If the dispute is not resolved within 60 days, the Director, TMA will issue an initial administrative decision and provide the manufacturer with opportunity to request reconsideration or appeal consistent with procedures under section 199.10 of this part. When the dispute is ultimately resolved, any refund owed relating to the amount in dispute will be subject to an interest charge from the date payment of the amount was initially due, consistent with section 199.11 of this part.

(4) Remedies. In the case of the failure of a manufacturer of a covered drug to make or honor an agreement under this paragraph (q), the Director, TMA, in addition to other actions referred to in this paragraph (q), may take any other action authorized by law.

(5) Beneficiary transition provisions. In cases in which a pharmaceutical is removed from the uniform formulary or designated for preauthorization under paragraph (q)(2) of this section, the Director, TMA may for transitional time periods determined appropriate by the Director or for particular circumstances authorize the continued availability of the pharmaceutical in the retail pharmacy network or in MTF pharmacies for some or all beneficiaries as if the pharmaceutical were still on the uniform formulary.