

## UF VARR Appendix for the **AUGUST 2013** DoD P&T Meeting

### Condition Sets for Uniform Formulary Voluntary Agreements for TRICARE Retail Refunds

#### (UF-VARR)

The following Condition Sets, as authorized at each listed UF Drug Class Page, identify the conditions under which UF-VARR quotes are to be submitted by the Company.

The Company must submit a separate, complete UF-VARR quote for each Condition Set that applies to the Company's pharmaceutical agents in a given drug class. The Company must record the Condition Set # that applies to a given UF-VARR quote in the appropriate blank on Table 1, Uniform Formulary Refund Quote.

The refund quoted will apply to the resulting UF-VARR if the quoted pharmaceutical agent is selected for inclusion on the UF in no worse than the formulary (2<sup>nd</sup>) cost share tier. The refund quoted is not contingent on the quoted pharmaceutical agent being selected for inclusion on the BCF or ECF.

**No grandfathering:** a prior authorization process, would require all patients, regardless of past medication history to complete an adequate trial of the step-preferred agent(s) before a non-step-preferred agent is provided.

**Suite:** Each manufacturer will be allowed to designate what strips are in their group of strips known as a suite. Only one bid submission per manufacturer will be allowed. All strips within a suite must have the same price.

#### **Medical Necessity for this class may include but is not limited to:**

1. The patient reasonably would not be able to use a formulary blood glucose meter and strips appropriately or effectively instead of the requested blood glucose meter and formulary excluded strips.
2. The patient has a documented physical or mental health disability requiring a special monitor (e.g. visual impairment).
3. The patient is using the Medtronic Mini Med Paradigm insulin pump with the One Touch Ultra Link meter (OneTouch Ultra test strips) or the patient is using the One Touch Ping insulin pump and One Touch Ping meter (OneTouch Ultra test strips).
4. The patient is receiving peritoneal dialysis or the intravenous immune globulin (IVIG) preparation Octagam and the provider is concerned about the glucose dehydrogenase-pyrroloquinolinequinone interaction (GDH-PQQ).

#### **Requirements:**

1. General Requirements

- Test strips
  - Must be available at all 3 Points of Service
  - Must be Trade Agreement Act-compliant
- Meters
  - Manufacturer must have a process to supply meters to beneficiaries at no cost.
  - Must be Trade Agreement Act-compliant

2. Meet the new minimum technical requirements

| Feature                | Minimum Requirements                                 |
|------------------------|--|
| Accuracy               | FDA standard   |
| Sample size            | $\leq 1$ microliter                                  |
| Alternate site testing | >1 site (palm, forearm, etc)                         |
| Result time            | $\leq 10$ seconds                                    |
| Memory                 | $\geq 250$ readings                                  |
| Ease of use            | Coding/calibration*, large visual display, dexterity |
| Customer support       | 24-hour phone help linet                             |
| Downloading capability | Mandatory  |

|                            |           |
|----------------------------|-----------|
| Data management capability | Mandatory |
|----------------------------|-----------|

\* Require low risk of coding/calibration errors; exclude meters with manual coding  
† 24-hour helpline required for OCONUS beneficiaries

The following NDC is in the Suite:

| NDC | Drug Name | Strength | Dosage Form | Package Size |
|-----|-----------|----------|-------------|--------------|
|     |           |          |             |              |

| <b>PEC Class: SELF MONITORING BLOOD GLUCOSE SYSTEMS</b>   |                                   |                             |  |
|---|-----------------------------------|-----------------------------|--|
| <b>Class Note(s): Each manufacturer may designate what strips are in their suite. Only one submission per manufacturer will be allowed. All strips within a suite must have the same price.</b> |                                   |                             |  |
| <b>Step Therapy Addendum: "No grandfathering" has been designated for this class.</b>   |                                   |                             |  |
| Condition Set #   | Category                          | One of (X) Number of Suites | Additional Refund per NDC<br>Percentage is Static<br>WAC *(Y%) |
| 1304BGNO1T2BS1X   | Tier 2,<br>Before Step<br>Therapy | 1                           |  |