Health Net
Medicare Programs

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December 8, 2008

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs Division of Regulations Development – C
Bonnie L. Harkless
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Ms. Harkless:

Attached are Health Net, Inc. comments on the CMS' proposed CY 2010 Formulary Submission files. If you have any questions on this submission, please do not hesitate to call me directly at (916) 935-1276.

Sincerely,

Alejandra Q. Clyde

Alejandra Q. Clyde
Manager, Compliance & Reporting
Senior Products Division
Health Net, Inc.

Draft 2010 Formulary Submission

Health Net, Inc. Comments

Comments to the CY2010, "List Of Changes To The 2010 Formulary And Supplemental Record Layouts (PRA)" section

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1. <u>Formulary File Record Layout Changes:</u>

1) **Comment**: The RXNorm_RXCUI in not an industry standard and is currently not housed within our system. The change to replace the NDC with the RXNorm_RXCUI field will create additional challenges to plans. If CMS' intent is to replace the NDC with RXNorm data in the Formulary Reference File, plans will need a crosswalk to cross-reference to NDC accordingly. Medispan, our current drug compendia, does not have a crosswalk from NDC to RxNorm data available. Without this, a significant amount of manual work will be required to quality check our formulary files.

   a) **RECOMMENDATION**: We highly suggest this change to be delayed until CY 2011. This will allow plans sufficient time to implement this new process within their existing systems and allow the drug compendia time to create the necessary cross reference files.

2) **Comment** The changes to the removal of the Quantity_Limit_Days field, and the Quantity_Limit_Amount field description which has been updated to indicate that the amount is based on 31 days; will require plans to make a number of operational changes in their internal processes

<u>3. Gap Coverage, Free First Fills, and Home Infusion Record Layout Changes;</u>

1) **Comment**: Same as the "Formulary File Record Layout Changes"

<u>6. Prior Authorization Record Layout Changes:</u>

1) **Comment**: Same as the "Formulary File Record Layout Changes"

2) Prior authorization criteria out on its websites

   a. **Question**: How will this change affect the plans posting of prior authorization criteria out on its websites?
   b. Will plans continue to post prior authorization criteria by a general drug name or prior authorization group description or will the requirement become more strict and burdensome with the requirement to include all the brand name, generic name, drug strength, and dosage form represented by the RXNorm_RXCUI field?
   c. **Comment**: IMPACT ON BURDEN: As you'll most likely agree, time is the most challenging barrier to quality assurance with regards to each formulary submission and resubmission. The new proposed requirement with the criteria to be submitted (and duplicated) for each affected RXNorm_RXCUI field will drastically increase the plans' burden to conduct adequate quality assurance reviews in the time allotted where prior authorization criteria are combined for multiple drugs under one group description. **RECOMMENDATION:** Allow plans to post prior authorization criteria by brand or generic name and/or prior authorization group descriptions.

3) Coverage_Duration Field Length 100 characters
   a) **Comment**: This field is too short to clearly state what the authorization limit is for each approved indication. Anzemet has the following FDA indications:
      i) Prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including high dose cisplatin.
      ii) The prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, including initial and repeat courses.
      iii) The prevention of postoperative nausea and vomiting (PONV).
      iv) The treatment of postoperative nausea and/or vomiting (PONV).

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The number of characters stating only the indications is 561. It is difficult to clearly write out each indication, the time for approval, and the Medicare Part B vs. Medicare Part D status, in 100 characters.

b) An abbreviated authorization limit can be used such as, "HEC/MEC:Part B:Within 48 hrs of chemo Part D: 48 hrs post chemo.PONV:1 day. RINV:Length of therapy". The limitation is that most patients will not be familiar with these abbreviations so it will be difficult to determine how long the drug will be approved for.

c) An attempt was made to clarify the authorization limit in the "Other_Criteria" field, but was told that this action was inappropriate in a memo and in Microsoft® Excel worksheets sent by CMS on Sep. 5, 2008 regarding Health Net's CY 2009 Prior Authorization Criteria.

d) **Comment**: This field is too short to clearly state what the authorization limit is for a drug that requires intensive monitoring. The authorization and reauthorization limit of Pegasys for Hepatitis C treatment is based on the viral load and genotype that is the standard of care (883 characters):
   i) Genotypes 1, 4, and 6
      (1) Initial authorization for 12 weeks
      (2) If viral load undetectable at 12 weeks, authorize for an additional 36 weeks.
      (3) If viral load remains detectable and there is at least a 2 log reduction at 12 weeks, authorize for an additional 12 weeks, and recheck viral load at 24 weeks.
      (4) If viral load is detectable at 12 weeks and there was not a 2 log reduction, no additional authorization.
      (5) If viral load is undetectable at 24 week recheck, authorize for an additional 24 weeks.
      (6) For members with Genotype 1,4, or 6 a detectable viral load and a 2 log reduction at 12 weeks a total of 72 weeks can be authorized if viral load undetectable at 24 weeks.
      (7) If viral load is detectable at 24 weeks, no additional authorization.
   ii) Genotypes 2, 3
      (1) 24 weeks. No additional authorizations beyond 24 weeks
   iii) Recurrence after liver transplant:
      (1) 48 weeks
   iv) Even if the authorization limit language is copied from DrugDex, "Consideration should be given to discontinuation of therapy if a virologic response (defined as undetectable hepatitis C virus (HCV) RNA) is not seen after 12 to 24 weeks of treatment or at least a 2log(10) reduction from baseline in HCV RNA titer by 12 weeks of therapy." It 270 characters.

e) **Comment**: Another example is for Avastin. It has the following indications: Colorectal Cancer, Non-Squamous, Non-Small Cell Lung Cancer, Breast Cancer, Ovarian Cancer, Glioblastoma Multiforme, Anaplastic Astrocytoma/Anaplastic Oligodendroglioma. Just listing the indications is over 100 characters. This does not include the actual authorization limit.

f) **RECOMMENDATION**: Increase the character limit to 1000.

g) **RECOMMENDATION**: Alternatively, allow the authorization limit to be clarified in the "Other_Criteria" field.

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December 5, 2008

Ms. Bonnie L. Harkless
CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Draft 2010 Plan benefit Package (PBP) Formulary Submission Public Comment Period

Dear Ms. Harkless,

Express Scripts, Inc. appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) changes between the CY 2009 and CY 2010 PBP and Formulary Files. On behalf of Express Scripts, I would like to offer the following observations and concerns in regards to this recommended change.

From a formulary management perspective, the move to RxNorm from NDC is problematic in several areas:

- When comparing CMS' Formulary Reference File (FRF) to the National Library of Medicine (NLM) data there are issues of inconsistent and missing data:
  - FRF NDCs have RXCUI values but when cross-referenced with NLM these NDCs do not have RxNorm data
  - FRF RXCUI values have label names where there is no label name in NLM data
  - FRF RXCUI values have chemical descriptors where there is no chemical descriptor in the NLM data
  - There are identical products that have different RXCUI values from the FRF and NLM
  - An NDC may have multiple RXCUI values where the FRF provides only one unique value.
- There are products that are completely missing from NLM data
- There are completely different products that have the same RXCUI, TTY and RxNorm descriptor values
- Products with 3 or more ingredients have limited or no RXNorm values
- NLM data implies a product status of brand or generic.
- The changes proposed are removing PA Description, then using RxCUI on the PA file. This will mean every RxCUI will need to have the criteria repeated. The files are going to be too large and it will be difficult to maintain consistency when you have the same criteria for 25 RxCUIs.

In addition to the above, there are several business and operational questions that remain unanswered. It is critical that these be address and CMS provided specific guidance for RXNorm to be successful.

- What is the process that CMS uses to populate the RxNorm data on the FRF?
- How often is RxNorm data updated via NLM and CMS? Today First Data Bank (FDB) data is updated daily in ESI systems. This is critical to the adjudication process
- Why are there discrepancies between the NLM data and FRF data? CMS must define the algorithm that plans are expected to use. In addition, the algorithm must be concrete in the short and long term in order for plans to integrate the process into their systems.
- NLM customer service has told Express Scripts (ESI) that their documentation is incomplete and not ready for publication. How can CMS expect plans to use RxNorm when even the NLM is not ready to apply the data?
- NLM offers customer service only via email. This process is not acceptable. Today ESI has account managers with our vendors that we interact with on a daily basis. Customer support is critical to ensuring we are serving our patients and health plans.

ESI will need several months up to a year to implement RxNorm into its automated systems and processes. If we are expected to submit formularies using RxNorm we will have to integrate those values down to the claim level.

From a Plan Finder File Perspective there are a few questions that remain unanswered:

- Will this have an impact on Plan Finder Files?
- Is CMS expecting to see the RxNorm or NDC when we return the PC, PF, RP file back to them through HPMS?
- Are clients who do not use our standard formulary going to have to subscribe to FDB to provide them with the RxNorm? How is client going to get RxNorm?
- Is the Tier level drug specific or RxNorm specific?

In summary, while RXNorm is a great concept, it is not in a state for daily usability by plans. It must be fully thought out, documented and serviced in order to be used on a daily basis. It must be mapped to internal systems. In order to do this it must be in a completed format with logic that can be integrated in a consistent and clear manner. We strongly disagree with using RxNorm in 2010. We feel it must be postponed until there is a clear algorithm for use as well as a clear path for customer support.

Thank you for reviewing our concerns.

Sincerely,

Snezana Grgic

Snezana Grgic, Pharm.D.
Clinical Product Manager
Express Scripts, Inc.

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Medi-CareFirst BlueCross BlueShield (S5766 & H2788)
Comments on 2010 Formulary File Record Layout Changes:
December 08, 2008

Formulary File Record Layout Changes:

- The Quantity_Limit_Days field has been removed.
- The Quantity_Limit_Amount field description has been updated to indicate that the amount is based on 31 days.

REASON WHY CHANGE IS NEEDED: These changes are needed to the formulary file to utilize standardize quantity limit submissions across all plan sponsors.
IMPACT ON BURDEN: Decrease in burden

Plan's Comment/Questions:
CMS is proposing a change to the quantity limit days & amount, as stated above, for 2010 formulary file. Per CMS, "Plans must submit the quantity limit amount for a 31 day period. The units for this amount must be defined by a unit measure e.g. number of tablets, number of milliliters, number of grams, etc. Plans are not to enter the number of syringes, bottles, or packages."

Due to availability of various drug formulations in the market, to provide flexibility to prescribers, and to provide comprehensible quantity level limits on plan's website there is a need to program & display quantity levels based on the quantity per copay or quantity per prescription in addition to quantity per day supply. Restricting display of quantity levels to a specific format (Qty/31 days) raises some questions and concerns. Examples below display these questions and concerns.

Example of quantity per copay: Our plan restricts Epi-pen injection to 2 pen injectors per copay. This amount should provide sufficient quantity to member per manufacturer guidelines. If the member requires additional Epi-pens to keep at various locations, plan will not prevent that; however member must pay additional copay for each additional 2 Epi-pen-injectors. How should plans submit the QL amount in this situation? Currently plan has the flexibility to display quantity level of 2 per 1 day.

Example of quantity per prescription: Our plan restricts Z-Pack 250 tablets to 6 tablets per prescription. Members are able to receive that quantity per prescription. If a refill is necessary, or a new prescription is written for the same drug but other diagnosis, member will be able to receive those as well with additional copay. Z-Pack 250mg, quantity limit of 6, 12, or 18 tablets per 31 days will not be true representation of the quantity limit. How should plans submit the QL amount in this situation? Currently plan has the flexibility to display quantity level of 6 per 1 day.

Example of display on Website:
Will plans be restricted to use the new format for display purposes on their website?
Displaying the quantity limit on website in the same format as the 2010 formulary file will not be comprehensible to the public. Medroxyprogesterone vial 150mg/ml is restricted to 1kit or 1 ml per 90 days; quantity limit will be submitted as 0.3 per 31 days per 2010 changes. Currently plan has the ability to display 1 vial per 90 days.
If allowed to display in other formats, then plans must keep a Quantity level for formulary file purposes and another for their website. This does not decrease the burden of formulary management as suggested by CMS.