Stephens, Carmen (OIC)

From: Edmonds Endo <edmondsendo@msn.com>
Sent: Wednesday, January 4, 2017 9:25 PM
To: OIC Rules Coordinator
Subject: R2016-19

Dear Mr. Freeberg,

I read through many of the letters that were sent in from various healthcare entities when this was first proposed and I have read through your changes. Here are my concerns:

1) I really wish you would separate "prior authorizations" for prescriptions and "prior authorizations" for procedures because they are not the same and I think there are enough differences that I do not think it is appropriate to encompass both under the same umbrella for the purposes of these rules.
   Personally, I would refer to procedures as "precertification" and prescriptions as "preauthorization" to differentiate. (but that's just me.)

2) WAC-284-43-2000 (2): "written clinical review criteria based on reasonable medical evidence."
   Here in lays the problem. Insurance companies have a tendency to get creative in their "reasonable medical evidence" when they don't what to pay for something regardless of what the prevailing "authorities" say. What is "reasonable medical evidence" to an insurance company can be vastly different than "reasonable medical evidence" to providers. The problem is nothing can be done about it without taking the matter to court, which most patients cannot afford so, usually, Though I have not had many that have had to go as far as a third party reviewer, my experience with the few I've had is that the reviewer does not address whether the plan's policy is sound. Whether the plan's criteria truly represents medical evidence or the prevailing opinion should be a mandatory part of the third party review process. Personally, I think that we should be able to submit insurance companies' coverage determination criteria to MQAC (Medical Quality Assurance Commissioner). They are making clinical determinations regarding patient care; they should be held up to the same sort of Quality Assurance a provider is.
3) WAC-284-43-2000 (4c): "Not routinely require providers or facilities to numerically code diagnoses or procedures to be considered for certification." No offense, but this is just nuts. Codes are our common language (not to mention how most people look things up). Prohibiting insurance companies from asking for codes is like calling the University of Washington to ask them about a patient without giving them any identify information other than the patient's name. You may or may not be talking about the same person.
   Do I like having to look up procedure codes for tests I order but don't personally bill for? No, but it is how I know the insurance and I are talking about the same test or procedure.

   My one thought, is not requiring the provider to produce all possible CPT codes that may be used for a procedure, just the "mother" code. For example, if a provider orders a CT, automatically allow for CT with and without contrast. This may not be the best example but, as we don't do many procedures, my exact experience is limited. The other possibility is that plans allow codes for what I call "sounds like." I had to do a predetermination for a procedure I was not familiar with at all. It was challenging selecting the right CPT code because some were similar. Plans should honor predetermination for services when the CPT billed may not be the exact one that was requested but the procedure is similar enough that the wrong CPT code may have been selected.

4) WAC-284-43-2000 (4) (d): "Not routinely request copies of medical records on all patients reviewed." This should be better clarified. I'm pretty sure I ***know*** what you are trying to say but, after reading some of the letters sent in, I don't think you are saying it very well and it will lead to headaches. So, what I ***think*** you are trying to say if a doctor provides the necessary information in a letter or in response to questions, the insurance company should not request ***physical*** copies of information the doctor references; which I've had happen (Thank you very much, Washington State Rx Services. I provided them a patient's 20 year cholesterol medication history in list format with the names of the medications, dates tried, and reason for failure. They told me they wanted chart notes….***20 years*** worth of chart notes I asked…. Oh no, just go through and pick out the ones relevant…. Gee, thanks.)
   If I am correct in my assumption behind this section, please save the insurance companies headaches later and clarify. I think simply adding "physical" before copies would make this a lot clearer and you won't have some future issue of offices telling insurance companies they shouldn't be requesting medical records. Also, I would add that this does not apply to an appeal request. Since the information may need to be sent to an outside party, it should be clear that actual copies of the medical records most likely will be required. Consider this: In a court case, the expert witness doesn't just go off of what the treating doctor might say in their deposition; they are going to what to review the patient's file for themselves. The same is true with an appeal with the insurance company. The third party reviewer is most likely going to want to review the file personally not just go off of a doctor's letter.
5) WAC-284-43-2000 (4) (i): "Not retrospectively deny coverage or payment for care based upon standards or protocols not communicated to the provider or facility within a sufficient time period ….." Please provide some definition of "sufficient." What is sufficient to the insurance company may not be sufficient to the doctor and then you are engage in battle to be paid. I can see an insurance company now: "What do you mean you didn't have sufficient time?! I told you 4 pm on Friday and it is now Monday" or what do mean "What do you mean 'Twenty four hours isn't a sufficient time?' "
   Please give some perimeters for "sufficient."
6) WAC-284-43-2000 (6) (c) (i): "Information about whether a request is approved or denied must be made available to the provider or facility, and enrollee. Issuers must at minimum make the information available on their web site or from their call center."
   Please include fax. We want to save time. I do not want to have to call to get the information nor do I want to login , input all the patient info, etc and so on to find out the response {and do it all over again if they haven't uploaded their response}. It takes two seconds to look at a fax, it takes ***at least*** 10 minutes to call and ***at least*** 5 minutes to look up the information on line. (At least do this for pharmacy prior authorizations).
7) WAC-284-43-2050 (2): "in accordance with the carrier's current clinical review criteria."
   a) Please add the word "published" between current and clinical. I had one insurance deny a prescription prior authorization and when I asked why I was told that the values I had given weren't within the last six months. I told them that there was absolutely no mention that the levels had to be done in the last six months in their criteria and that the levels provided met all the criteria that they asked for per their published criteria. (One level had been recent and one level had been prior to six months for a condition he has had for a while).
   b) I have an issue with the term "current." Here's the scenario: Patient has been on testosterone replacement therapy for six years. His pretreatment testosterone total was drawn at 11 am in the morning and it was 150 (say normal is 291-750). The insurance ***now*** requires two testosterone levels be drawn prior to treatment and they have to be done between 8 am and 10 am in the morning. By using the word "current" the insurance company ***could*** require the patient stop the testosterone therapy, wait, and then do repeat labs on two separate days between 8-10 am. This is a problem.
8) WAC-284-43-2050 (4): "current and accurate online prior authorization system."
   Please, I am begging you to rephrase this. What you state here does not represent what you state in (a) (b) (c) (d). And again, please differentiate between pharmacy prior authorizations and procedural prior authorizations. Your subcategories to this section are more likely to be used in association with a "predetermination system."

9) WAC-284-43-2050 (5): "Must have an electronic process that is browser-based." Just NO!!! I cannot more emphatically state that. No MUST!! Procedures, maybe. Prescriptions: NO, NO, NO, NO!!!
    a) Do you have any idea how much longer it takes to do these pharmacy prior authorizations on line? For example, Premera recently started using a third party system and, it states, this is the quickest method. Uh, no. It takes about 10-15 minutes. (Multiple that by how many prior auths you have to do in a day).
    b) If you push something that companies are not equipped to do, it will end up making our lives miserable. The greater the haste, the greater the hindrance because haste is ever the parent of failure. Just because an insurance company has an online system doesn't mean the system doesn't stink. OptumRX is horrendous (there is not a word strong enough to tell you how awful their system is) to use. I have yet to successfully do a prior authorization through their system. At our recent community office manager meeting I mentioned the words "United Healthcare" (OptumRX) in connection to their website; there was an involuntary pained groan through the whole group. Do you have any idea how miserable offices will be having to contend with crummy systems? Requiring plans to come up with programs to support what you've outlined in this law in such a short time frame, using current systems that aren't necessarily compatible to meeting those requirements, and haven't been done on the scale you are asking, in a time when the plans are losing money, do you really think these systems are going to be great? Let's get the them to even have decent websites ***before*** we start worrying about getting them to have an electronic process.
    c) Do not drive up the cost of healthcare by making the insurance companies implement systems that they are not set up for.
    d) If you don't want them to routinely ask for medical records then why on earth are you requiring them to spend a lot of money on something they shouldn't need very often and why would you require that they pay for copies of medical records if all the office is doing is sending them electronically?

Yes, I agree that transparency is needed but give them some basic guidelines and let them come up with reasonable ways to comply. I'm not as well versed in procedural prior authorizations as I am in pharmacy but I do believe that many plans already offer some sort of predetermination system on their website. Let's focus on even getting these to work before you ask for things on the scale you are requesting in this rule. (The one thing that they should be required to include though is calculation of "facility fee" into their predetermination). Pharmacy transparency is the biggest problem. What is needed:

1) Formulary search tool on their website or through a third party. (There are third party companies, that are free, that are working on this. Get the insurance companies to work ***with*** them. My personal favorite is MMIT formulary search- at formularylookup.com) No formulary lists because they are a pain to search through. Not everyone has the same method of labeling their "categories" so you are just searching through everything. For example, do they list diabetic drugs as Anti-hyperglycemic agents or under Endocrinology, etc…..Painful process.
2) If there is more than one formulary, the search tool should allow you to select the plan the patient is on. (Like X1 vs. A1)
3) When bringing up a selected drug, it should state whether it is formulary or not, if any prior authorization is required, and what the criteria is ***and,*** IF it is losing formulary status is the coming month or two, what the new preferred medication will be.
4) Require the insurance company to state, on the medical insurance card, whether the patient has prescription benefits through them or not (Like Regence listing RX then Y or N). This will let provider know whether or ask for the patient's pharmacy benefit manager card. (Patients often don't realize that there is a difference).
5) If the pharmacy benefits are handled by the same entity as the medical benefits, require the insurance companies to list, on the card, what formulary is on. (Like Premera will say

X1). United Healthcare is horrible about having different formularies but you can't tell by the card which formulary you should be looking at. (That's if you can locate a formulary list at all without them trying to sell you a plan….Good luck).

I will say the absolute best prior authorization (prescription) system I have ever dealt with, hands down for speed and clarity was Regence's prior authorization forms BEFORE they went to OmedaRX. (http://www.formularysolution.com/forms/product/4/20090520055741.pdf) This was absolute perfection. Fill it out, print it out, and fax it in (and they didn't usually require chart notes). The Express Scripts online forms that you could print out weren't bad either.

10) WAC-284-43-2050 (5) (a): With regards to the last few words of this section, "a notice regarding the enrollee's appeal rights and process", please add that it must include the address, fax, ***and phone*** number of appeal department directly.
One plan in particularly has absolutely no way of faxing or calling them so you have to send the appeal in and wait. Usually, you never hear back. Plus, it's annoying when they do provide the phone number but it is the same phone number for everything else and there are no phone tree options for appeals (and they won't let you talk to a representative till you waste several minutes of your life listening to eligibility and benefits that you didn't need to know).
11) WAC-284-43-2050 (8) (a): Please include that a carrier must inform the provider or facility how to request the receipt of each document. (Otherwise, it's going to be one of those things were you can't find the person who knows how to provide it or trying to find that person is going to be so laborious that the provider gives up).
12) WAC-284-43-2050 (8) (b): Please include "if requested." If I don't want this information, don't send it.
13) WAC-284-43-2050 (9): "A carrier or its designated or contracted representative that requires prior authorization must allow a provider or facility to submit a request for a prior authorization at all times, including outside normal business hours." This is an interesting one and I really don't see the point of this. 1) If the system is an electronic process, you could submit prior auths anytime. 2) Already you can submit prior authorizations or precertifications at any time via fax. Doesn't mean anyone is there to receive it but it will be there when the company next opens.
14) WAC-284-43-2050 (11): This section is again a place where I think that a distinction between prior authorizations for prescriptions and prior authorizations for procedures would be advantageous. Prior authorizations for prescription standard should be 3 business days and expedited should be 24 hours. Where procedures have in "emergency" type clauses, prescriptions do not and you can't get the prescription until you have an approval.
15) WAC-284-43-2050 (15): "A carrier must reimburse reasonable costs of medical records duplication for reviews." I don't agree with this but, if you really want this you need to define "reasonable" and I would state that it only applies if the records needed to make the determination exceed "x" amount of pages (like 20 pages) and (maybe) should not apply if the records are electronically transmitted (there is no reason to be charging an insurance company for duplication of records if all the office has to do is click a couple of buttons to send them. If there is more involved to this process than that might be a different matter).
16) WAC-284-43-2050 (17) (b): "For pharmacy services, a carrier or its designated or contracted representative must recognize a prior authorization for the initial fill, or until the prior authorization process of the new carrier or its designated or contracted representative has been completed." The intentions behind this are good but this is insufficient. This should be removed from this section and its own section should be created to state this: "For pharmacy services, a carrier or its designated or contracted representative must provide a one-time temporary supply of the current drug the enrollee is on during the first 100 days of being on the plan" and "For pharmacy services, when a carrier or its designated or contracted representative makes changes to it's formulary, the carrier or its designated or contracted representative must provide a one-time temporary supply of the current drug the enrollee is on during the first 100 days after formulary status has changed." I have had times when patients pick up their insulin one month and then go in the next month and can't get it because it is no longer the formulary option. What if a patient needs to be on that particular insulin? (It's uncommon but it does

happen). Then everyone is scrambling to get it approved and fast. Medicare already allows a temporary fill any time a formulary changes or a patient switches PART D plans; typically it is a 30 day supply but don't put the words "30 days" in there because not everything can be obtained in exactly 30 day portions.

17) WAC-284-43-2050 (19): "Any carrier changes to a prior authorization procedure constitute a change to a provider or facility contract……and must be made as an amendment."
    1) Shouldn't it be "constitutes"?
    2) What do you mean by this? Do you mean the criteria that the prior authorization is based on or do you mean the way the prior authorization is done (or both)?
18) WAC-284-43-2060 (2): You should include: "The enrollee presents the provider or facility with the incorrect insurance information."

Now we get to the things that are missing:

1) "A carrier or its designated or contracted representative may not ***exclude*** any medication from its formulary when it belongs to a class of medications that is covered." This is huge. Excluded is different from non-formulary. It means that under no circumstances will a plan cover that particular drug. They are making categorical treatment decisions without any consideration of individuality of the patients. The one plan that loves to exclude is also the plan with the "black hole" benefit appeal process I mentioned above. You have to send your appeal to a P.O. Box and you will never hear a decision. There is no phone number or fax number to this "department," just the P.O. Box. The plan claims that exclusions are situations where medications offer "no additional clinical and/or financial value over other options in their class." Here are the problems with that: 1) No two drugs in any class are completely identical (98% of the time). They can't be because of patent issues. 2) Financial aside, there are other matters besides "clinical" that come into play, like tolerability for one. I've seen patients try and fail every formulary option available, yet they cannot be on the medication that works for them because it is excluded. I've dealt with an insurance company that excluded the use of insulin pens (in favor of insulin vials) and I had two patients that desperately needed the pen device because of visual impairment or issues with dexterity. Nothing could be done; the pens were excluded. Looking ahead, I notice this same plan has excluded three types of insulin this year. The one insulin I can potentially understand; it is biosimilar to the preferred medication (it is the same protein sequence). However, the other two insulins are not identical to the preferred mediation and they do have there "niche" in patient care that is unique to them. With insurance companies (or pharmacy benefit managers) excluding these medications providers are not afforded the opportunity to make their case for an exception. One example was a patient that was place on insulin C, the pharmacy benefit manager said he couldn't have that one unless he tried and failed insulin A ***and*** B. It was explained to them that the patient had failed insulin A, and by default, insulin B because their mechanisms of action were similar enough to know that the desire outcome could not be achieved. Insulin A and B were no longer on the table for this patient, the choices were at this point were Insulin C or D and insulin D was causing episodes of mild hypoglycemia (low blood sugar); fortunately, this patient was a Medicare patient so there were no exclusions but, had he been commercial, there would be no good options available to him. That's just wrong. Please forbid this habit of "excluding." They can require a prior authorization if they want but never should a medication, in a covered medication class, be excluded.
2) A carrier or its designated or contracted representative will reimburse to the provider a nominal fee for all step therapy requests (pharmacy) in which the doctor has met the expected criteria for step therapy prior to initiating the request. I'm not talking about the prior authorizations; I'm talking about the step edits that are getting beyond ridiculous. I had to do a step therapy request for a patient that we put on Janumet. The insurance company wanted to know if the patient had tried and failed metformin. Ummm, 1) Metformin is the "met" in Janumet. 2) Have you not been paying the claims for her metformin for the last two years? Then, when that criteria was satisfied we were asked if the patient had tried and failed taking 1 tablet of Janumet 50/500 mg because putting her on ***1*** tablet a day "is appropriate before titrating her up to two." Again, ummmm, she was ***on*** metformin 1,000 mg prior to starting the

Janumet. If we start with one a day we are going backwards in her metformin dosing (she'd be on 500 not 1,000 mg). *Sigh* The whole thing is so idiotic.

3) When a carrier or its designated or contracted representative changes its formulary they must communicate to the enrollee and the provider or facility the new preferred medication in that same drug class.
   CVS Caremark sent out letters to patients in December 2016 telling them that: "…..Changes are being made to the list of medications covered under your pharmacy benefit plan. One or more of your medications….will no longer be included on the list." Then below they listed "lower cost" medication: Generic Glucophage, Generic sulfonylurea or "higher cost" medication: Trulicity. This resulted in much confusion for the patients and a long of extra time for the provider's staff. 1) Generic Glucophage and sulfonylureas are not the same drug class as Trulicity and do not do the same thing. 2) Before they can even obtain a GLP-1 agonist (Trulicity) they have to try and fail, at the very least, metformin (generic Glucophage) so implying to a patient that it is a cheaper, equal alterative to the GLP-1 is just stupid because the very use of the GLP-1 indicates the patient has failed or has a contraindication to metformin. 3) Some of these patients are using the "lower cost medications" in ***conjunction*** with the GLP-1 agonist. 4) I still don't know what the preferred GLP-1 agonist is for CVS Caremark patients in 2017 because, even when I called (in December), they couldn't tell me.
4) A carrier or its designated or contracted representative must offer "tier exceptions" for any enrollee that does not tolerate the preferred medication or the preferred medication is contraindicated.
   Many plans, including Medicare Part D plans, offer tier exceptions already but not all do. This does not apply to making preferred brand names first tier but applies to making non-preferred medications preferred for a patient when the preferred medication is not tolerated or contraindicated. For example, we had a patient with hyperlipidemia (high cholesterol). The generic medications did not provide her with enough LDL reduction on their own so we were left with the choices of Crestor (a brand name statin at the time) or adding Zetia (another brand name cholesterol lower agent) to atorvastatin 80 mg. Problem was both Crestor and Zetia were non-formulary so she would be left with 50% of the cost of the medication (per her plan benefits). We applied for a tier exception and demonstrated that the formulary options were not enough to reach therapeutic goal and how would they like us to proceed. We told them that she could not afford 50% of the medication cost so we could either allow her to take atorvastatin by itself and be inadequately treated or they could allow a tier exception for either the Crestor or the Zetia. The tier exception was granted. If her plan had not been one to allow tier exceptions, she would not have been inadequately treated because she simply couldn't afford to pay 50%.
5) When a formulary medication changes a carrier or its designated or contracted representative must honor all new start prescriptions for upcoming preferred medication from the time the insurance company publishes notice of the change.
   Its frustrating when you want to start a patient on a new medication and you know that you will have to change them in 20 days because their formulary is changing. It didn't use to be such a huge problem but the insurance companies are changing formularies more frequently.
6) Tier exceptions shall be issued based on class and not based on drug. Example: Plan only allows Byetta (as a GLP-1 agonist). The patient has tried and failed Byetta. The plan will approve the use of the another GLP-1 but will not approve a tier exception because the patient has not tried and failed ***all*** the value based tiers. The drugs in the value based tiers belong to other classes and have a completely different function in diabetes management. This is a major problem with Uniform Medical. MAJOR PROBLEM. Uniform Medical has one of the highest non-preferred tier costs I've seen (50% of the cost of the drug). So if the patient cannot take the preferred medication, and the value tier options that they haven't tried are not appropriate, you tend to have difficulty getting the patient to take their medication because of cost. Also of note, Byetta (and its cousin Bydureon) are the only GLP-1 agonists that should specifically not be used in patients with impaired renal function. (See #7).

7) If a preferred medication is contraindicated in a specific patient population (such as renal impairment) the plan must provide, if available, another medication <u>of the same class</u> that is not contraindicated at the <u>same cost to the patient</u> as the preferred medication that is contraindicated.
8) A carrier or its designated or contracted representative cannot, as part of their step edit process, require an enrollee to try and fail a medication that contains a FDA black box warning.
9) When transmitting a denial of coverage to a pharmacy, a carrier or its designated or contracted representative, must provide the reason for the denial and the **appropriate** phone number **specific** to the party that handles the prior authorizations for the patient's plan. It took me thirty minutes the other day to tract down the phone number of the people that handled the prior authorizations for a patient's plan. Annoying.
10) A carrier or its designated or contracted representative must contain a pharmacy prior authorization option on their phone prompt. Very few plans have an option for pharmacy benefits in their phone tree and it is incredibly annoying having to listen to eligibility and benefits before they will let you speak to a representative that can transfer you to the pharmacy prior authorization department.

11) Please require that insurance companies ***must*** information patients, if they call, that their provider must call and see ***if*** they ***meet the authorization criteria*** for the medication they are inquiring about. Right now, some plans (two I can think of without blinking) tell patients: "All your provider has to do is call us." I cannot tell you how frustrating it is trying to explain to a patient that they don't meet the criteria and we have to change their medicine. "They said all you had to do was call…." "I know what they said but they {insurance company} also have a criteria that must be met before they'll approve it and they are telling us you don't meet it." "You must not be doing it right, they said all you had to do was call." It is SO frustrating.
12) A carrier or its designated or contracted representative must allow an enrollee to obtain the non-preferred glucose test strips at the preferred rate if they are using them in conjunction with an insulin pump.
    Some plans are actually pretty good about this but others will allow a patient to use non preferred test strips but charge them a higher copay. Typically the insulin pump the patient is using is the preferred pump on the insurance plan but the glucose test strips that the pump communicates to may not be.

I'm sure I'm missing things but deadlines don't wait. Thank you for the opportunity to bring these matters to your attention. I don't think I can stress enough that I think that requiring insurance companies to have the type of electronic processes that you are requesting at the present time, to the extent that you are requesting, is a very bad idea. Medtronic Minimed is coming out with the first "artificial pancreas" this spring. This didn't just happen overnight. It has taken at least 14 upgrades to get to this point. They started with what they could do and then upgraded from there expanding their technological capabilities as their understanding and knowledge grew. What do you think that closed loop system would have been like if they'd created it back when they made their first insulin pump? Let's start with some basics with these plans (like formulary search tools and clear easy to find prior authorization criteria) first before we worry about completely electronic systems. Thank you for your time and consideration on my opinion.

Sincerely,

Nancy Pfeil

P.S. Just so you know, Washington State's own Uniform Medical is probably the plan furthest away from accomplishing what you ask. They are the ONLY plan I have to CALL to get a prior authorization (pharmacy) form sent to me and they are the second hardest plan to determine formulary and prior authorization (pharmacy) criteria for online.