Testimony for Step Edit

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I am a practicing rheumatologist in Fayetteville NC and have been practicing there for 27 years. Every rheumatologist in NC takes caring for their patient's seriously , implementing superb care for excellent outcomes as important and the overall health of the patient as pertinent responsibility. The challenges of caring for chronically ill patients has gotten worse with the additional burdens of medication acquisition hurdles that delays and frustrates the patient and the physician. For our patients the Step Edit model does not work. Our medications are unique proteins that require care in selection and monitoring. The Step Edit system exists to get cheaper therapy for a beneficiary but this is not a great way to take care of patients with rheumatic conditions. At this time transparency and time efficiency is not possible with the current system and getting an exemption is timely and not in the best interest of the patient.

Today, I would like to give concrete examples of the challenges the rheumatologists in this state face every day with caring for patients with chronic rheumatic conditions. I would like to offer solutions for these barriers. I would like to frame a model for legislation to aid all of our patients gain the therapy they deserve in a timely fashion.

The current Step Edit imposed by insurers centers around maintaining the least expensive therapy without actual evaluation of the individual patient and their unique needs. Lower cost of care is important to all players in this arena.

I will give examples of the current cost saving models that make no sense.

1. Previously tried and failed a drug
   Patient has RA and has been taking Enbrel for 2 years and has lost clinical response. Their insurance has partnered with a PBM and the formulary asks for Enbrel to be used first. I am trying to change to another therapy with a different MoA. Several weeks of PAs and appeals ensues with the patient suffering and my staff using valuable time to gain access for another therapy.
2. Drug is expected to be ineffective based on medical history
   Patient has RA and poor prognostic factors with xray changes showing damage. Insurers are asking patient to have a trial of Methotrexate for 12-16 weeks first. I know that the patient needs a bDMARD or small molecule for therapy. Wasting time on this therapy is delaying patient 's good care and enhancing progression of disease.
3. Patient is stable on a current therapy
   Patient has RA for 4 years and has been having good clinical response to Orencia. Insurance changes and notes that Orencia is not on the formulary. A Rx is rendered to continue this and denied because the patient's pharmacy benefit no longer sanctions this product. I am expected to change the stable patient to another product that I can not predict the patient's outcome.

4. The drug is contraindicated or would likely cause an adverse reaction
   A young RA patient has been told she has MS and the use of TNF blockade therapy is contraindicated as this will cause the MS to worsen. Patient's formulary requires use of MTX and if bDMARD needed Enbrel is first line.
5. The treatment is not in the best interest of the patient
   Older RA patient has history of previous successfully treated cancer. RA disease activity has advanced and Rituxan is the drug recommended. Patient's pharmacy benefits dictate Humira as first choice.

   These examples outline the daily challenges with care for these complicated patients.

At this time a workable solution would be to formulate legislation that allows transparency and timely exceptions to Step Edits. There should be 5 automatic exceptions to Step Edit protocols.
-Previously tried and failed drug
-The drug is expected to be ineffective based on medical history
-A patient is stable on a current medication
- The drug is contraindicated or would likely cause an adverse reaction
- The treatment is not in the best interest of the patient

In addition, the model legislation should include provisions that require clinical review criteria for the development of the step protocols (have a rheumatologist or other specialty physician review and be part of the process); limited time frames for insurer to respond to step therapy override requests (72 hours). These measures will enhance the process of getting these needed medications to our patients.

Thank you for your time and the NCRA and all rheumatologists in NC look forward to your cooperation in this matter for the care of our patients.