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INNOVATIONS IN MEDICAID DRUG UTILIZATION REVIEWS: CLAIMS SUBMISSION STANDARDS TO SUPPORT VALUE BASED CONTRACTING

Background

The promotion and reporting of innovative practices under the umbrella of the Medicaid Drug Utilization Review Program (DUR) is receiving increased attention from the Center for Medicaid and CHIP Services (CMCS). The focus is on approaches to innovate, streamline and increase efficiency of Medicaid programs while increasing the quality of care for beneficiaries. In June 2020 CMS proposed rules to create flexibility for value-based contracting (VBC) in Medicaid to allow the outcomes-based pricing (value-based purchasing) seen in commercial plans to flourish in public plans to assist greater access to medications. Comment period 30 days. Comments received but no final rule.

Purpose

A commitment to greater flexibility and push to VBC give a significant window of opportunity to put forward proposals for minimum standards to support formulary assessments of new and competing therapies. The proposed standards would effectively relegate ICER to the sidelines. The models developed by ICER are not relevant to VBC. They are static, imaginary, one-off models that fail to support the standards of normal science where claims (the center-piece of VBC) are not credible, nor empirically evaluable or replicable. The added bonus is that the QALY can be abandoned. This fails the required axioms of measurement theory and any thought of fair pricing cost-per-QALY threshold have to be abandoned as well. At the same time because of the lack of dimensional homogeneity, multiattribute utility scores can be abandoned along with patient reported outcome measures that fail measurement standards. We can also disabuse ourselves of the blanket claim that a product is ‘cost-effective’.

If a value-based contract is to have any meaning, if it is not to be challenged, then the claims agreed for that contract must be credible, empirically evaluable and replicable. Otherwise the contact is a waste of time. Imaginary claims have no role.

The purpose of these submission standards is to establish a firm basis for the claims that will be part of a value based contract. It is not the intent here to write value based contracts but to ensure that the claims to be tracked and reported meet the standards of normal science. Certainly there will be negotiation over the claims before agreement on the final set of claims is achieved.

The standards proposed are patient centric: claims under VBC will be specific to target patient groups within disease areas (e.g., rare disease, target groups with disabilities, caregivers) and will be evaluated and reported for the patient group under a vale assessment contract. An important aspect will be claims that address the needs of patients and caregivers: does a new therapy contribute to improving quality of life in meeting the needs of patients and caregivers? The claim here would be in terms of a disease specific quality of life instrument, with potentially separate instruments for patients and caregivers.

Claims

All claims must meet the standards for fundamental measurement in terms of how they are measured and the claims themselves. The key requirement, following the standards in the physical sciences, is that claims must refer to single attributes. Multiattribute claims are not acceptable. Each claim must be consistent with the axioms of fundamental measurement for an interval scale response or a ratio scale response. There must be an audit for each instrument to ensure it meets these standards (e.g., for interval measures it must be demonstrated that the measures meet Rasch Measurement standards). Ordinal claims are not acceptable.

Claims Protocols

Under any formulary submission, where requested by the state Medicaid formulary, there will be a mix of single attribute claims: clinical, quality of life, resource utilization. Claims to be contracted will be agreed by the manufacturer. Each claim must be accompanied by a claims assessment protocol detailing how the claim is to be tracked, the time frame and reported.

Evidence Base

The manufacturer must detail the evidence base for claims tracking. This might be a target patient specific registry or a combination of registry and administrative data. If a sample of patients is proposed then this must be defined. If possible, the evidence base must be capable of supporting ongoing disease area and therapeutic class reviews.

Dispute Resolution

Inevitably, there will be contractual disputes. Hence the importance of a solid contract drawn up by professionals with an agreed dispute reconciliation process.

Commonality

In some cases, the manufacturer might agree with individual state Medicaid formularies, that the claims are not specific to a single target patient group in a state Medicaid but are common across state Medicaid target populations. In this case there might be agreement to accept claims from one target patient group and apply across patient populations in different states.

A Clean Slate

Our purpose is to argue for a clean slate; dispensing with the ICER dross and proposing a Medicaid formulary request for submission package. Fortunately, the structure and content for a package is complete in the recently published Minnesota formulary submission guidelines.

Primary Care Engagement and Quality Improvement

It is important to see these proposals for effective value based contracting in the context of activities such as those directed by the National Committee for Quality Assurance (NCQA), value programs to drive greater primary care engagement (e.g., practice performance against benchmarks, cost, savings, improvements in care quality) together with the CMS Physician Quality Reporting System (PQRS) and the Merit Based Incentive Payment System (MIPS). The difference is that the value assessments proposed here under VBC is for comparative product performance to support pricing and access. A product can only be judged in terms of its impact on target patients in real world treating environments. ICER's models that attempt to short circuit this by creating imaginary I-QALY based models to support formulary decisions on pricing and access are fail basic standards. Value claims capturing a complex of clinical, quality of life and resource utilization attributes are the only basis for initial and ongoing product value assessment, provisional pricing and consequent pricing reviews.

Overview: Claims Criteria

There are four key principles:

- Claims must meet the standards of normal science
    - Claims must be credible, empirically evaluable and replicable
    - Claims must meet the standards for fundamental measurement
    - Claims must be dimensionally homogeneous or unidimensional
- Claims must be for single attributes defined for clinical outcomes, quality of life and resource utilization
- Claims must be specific to target populations within disease areas

- Claims must be accompanied by a protocol detailing how they might be evaluated or how they have been evaluated

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