







New York Medicaid Program Basic Benefit Review Work Group



Agenda

- Introductions and Review Agenda
- Review materials
- Principles for Benefit Design
- Overview of Opportunities: OHSU
- Drill Down
 - Underuse
 - Overuse
- Benefit Review Process
- Next Steps



Vision

- New York Medicaid will have an evidence informed benefit package which promotes high quality, efficient, and effective services that improve health and health care outcomes for its members.
- A transparent, sustainable and iterative process to accomplish this will be created that is inclusive of internal and external stakeholders as well as content experts in health care benefit design, implementation, and evaluation.



Mission/Charge

▶ 1. Group will review current Medicaid benefits including an overview of coverage criteria (if any), copayments (if any), within Fee-for-Service (FFS) and Managed Care for specific suggestions regarding ways to develop and promote evidence informed, cost effective health care services within the parameter of overall budget neutrality for the Medicaid program.



Mission/Charge

▶ 2. Group will make specific suggestions regarding the creation of an effective, transparent, efficient, and evidence based/informed process for making future and on-going benefit decisions in response to new codes, new procedures, new technologies, and other advances in medical/behavioral knowledge regarding effectiveness and costs within the parameter of available resources in the Medicaid program.



Review Distributed Materials



Draft Principles for Benefit Design



Principles for Benefit Design

- Equity
- Priority Setting
- Maximize population health
- Evidence over opinion
- Criteria for evaluation
- Criteria for reduction, elimination, limitations
- Patient centered outcomes

New York State Department of Health MRT Benefit Redesign Workgroup

Research Overview and Potential Areas of Review
As Submitted by the State University of New York and
Center for Evidenced-based Policy
at Oregon Health and Sciences University
September 14, 2011

Overview of Research Process

- Defining the question
- Searching the literature
- Appraising the literature
- Synthesizing the evidence
- Peer review

Defining the Question (PICO Plus)

- Population
- Intervention
- Comparator
- Outcome
- Plus
 - Policy context and analysis
 - Cost effectiveness

Searching the Literature - Strategies

- All relevant literature
- Limited searches
 - English language
 - Core sources
 - Most cited *
 - Most recent *
 - * Danger

Appraising the Literature

- Hierarchy of evidence
 - 1. Meta analysis of randomized controlled trials
 - 2. Systematic review of RCTs
 - 3. Individual RCT(s)
 - 4. Observational studies (diagnostic accuracy)
 - cross-sectional, cohort, case-control
 - 5. Basic science research and clinical experience
 - Guidelines

Synthesizing the Evidence

- Summarizing good quality results
- Meta analysis of good quality similar results
- Rating overall strength of evidence (next slide)

Overall Quality of a Body of Evidence (GRADE)

Quality of evidence	Study Design
High quality (⊕⊕⊕⊕)	Randomized trials (SR/MA of RCTs)
Moderate quality (⊕⊕⊕)	Single trial, trials or SR with minor flaws
Low quality (⊕⊕)	Observational studies
Very low quality (⊕)	Expert opinion (GOBSATT)

Overall Quality of a Body of Evidence (GRADE)

Quality of evidence	Impact of further research:
High quality	Very unlikely to change the estimate of the effect of the intervention or our confidence in that estimate
Moderate quality	Likely to have an impact on our confidence in the estimate of effect, and <i>may</i> change the estimate
Low quality	Very likely to have an impact on our confidence in the estimate of effect and is <i>likely</i> to change the estimate
Very low quality	Any estimate of effect is very uncertain

Peer Review

- Selected experts
- Open review

How States Use Evidence

- Missouri hi-tech imaging
- Oklahoma terbutaline pumps
- Alabama maternity care
- Washington health technology assessment and dossiers
- Minnesota stakeholder process

Overview of Examples

- Coverage Policy Categories
 - Never Event
 - Automatic Coverage Limitation
 - Never Event for Specific Populations
 - Quantity or frequency limitations
 - Prior Authorization
- Coverage with Evidence Development

Summary of Topics

Topic	Never Event	Coverage Limitation	Prior Authorization Recommended
Interventions for Chronic Low Back Pain		X	X
Elective Delivery: Induction of Labor less than 39 Weeks		Х	
Elective Delivery: Cesarean Section less than 39 Weeks		Х	
Self-Monitoring of Blood Glucose for Type 2 Diabetes		Х	
Insulin Pumps			X
Real-Time Glucose Monitoring for Type 1 and Type 2 Diabetes Mellitus	X		X

Summary of Topics (Cont.)

Topic	Never Event	Coverage Limitation	Prior Authorization Recommended
Coronary Computed Tomographic Angiography		X	X
Functional Electrical Stimulators for Spinal Cord and Head Injury, Cerebral Palsy, and Upper Motor Neuron Diseases	X		
Vagus Nerve Stimulators for Depression		Х	
Proton Beam Radiation	X		
Arthroscopic Surgery of the Knee for Osteoarthritis		Х	
Terbulataline in Preterm Labor		Х	

Interventions for Chronic Low Back Pain

Category: Coverage Limitation or Prior Authorization

Overview
Low back pain (LBP) is a common condition that is categorized into three classifications based on symptom duration: acute (six weeks or less), subacute (6 to 12 weeks), and chronic (12 weeks or more).

Prevalence

LBP is the second leading cause of physician visits and hospitalizations, with estimated yearly total costs accounting for \$100 billion of US healthcare spending.

Evidence

No good quality evidence of efficacy for prolotherapy, intradiscal steroid injection, facet joint steroid injection, systemic corticosteroids, or traction (continuous or intermittent). No evidence to support advanced imaging in most cases (red flags only).

Policy implications/levers

 Consider "coverage limitation (never)" for prolotherapy, intradiscal steroid injection, facet joint steroid injection, systemic corticosteroids, or traction (continuous or intermittent) and prior authorization for advanced imaging.

Elective Delivery: Induction of Labor Less than 39 Weeks Category: Coverage Limitation

Overview

Induction of labor is frequently used to hasten delivery of a child. At present there are very few indications for induction that are supported by good quality evidence.

Prevalence

- Nationwide about 45% of all births are covered by Medicaid
- Overall US induction of labor (IOL) rate > 22% (2006)

Evidence

- Use of induction, particularly among nulliparous women and those without a favorable (ready for labor) cervix, is associated with increased use of health care resources, longer labors and increased use of cesarean delivery, poor neonatal outcomes (especially when done before 39 weeks completed gestation).
- There is increased morbidity for infants of mothers electively induced prior to 39 weeks of gestation, including higher rates of conditions requiring admission to a neonatal intensive care unit.

Policy Implications/Levers

- Consider "coverage limitation (never)" and require elective induction of labor (EIOL) at < 39 wks have a
 documented medical indication (consider "hard stop" policy)
- States can audit charts or vital statistics data to confirm indications
- Statewide quality improvement collaboratives can include "bonuses" to hospitals that control EIOL

Elective Delivery: Cesarean Section Less than 39 Weeks Category: Coverage Limitation

Overview

The rate of cesarean sections (CS) has been steadily increasing. Cited reasons include maternal preferences and characteristics, provider preferences and practice patterns, institutional factors, ambiguous indications and guidelines for CS, and fear of litigation.

Prevalence

- Current nationwide cesarean section rate is about 1/3
- Nationwide about 45% of births are covered by Medicaid
- Between 4% and 18% of primary cesarean sections in the United States are <u>elective</u>

Evidence

- Maternal outcomes are longer hospital stays and higher risk of abnormal placenta and bleeding in subsequent pregnancies
- Neonatal outcomes are increased NICU admission and increased risk of respiratory problems

Policy Implications/Levers

- Consider "coverage limitations (never)" for elective Cesarean delivery < 39 weeks.
- Cesarean delivery must have a documented medical indication.
- States can audit charts or vital statistics to confirm indications.

Self-monitoring of Blood Glucose for Type 2 Diabetes Category: Coverage Limitation

Overview

- Diabetes mellitus (DM) is a serious chronic disease with significant morbidity, mortality, and cost.
- Of the 17.9 million people with diagnosed DM in the United States, 2.2 million (14.5%) use insulin only, 10.3 million (57.6%) use oral medications only, 2.6 million (14.5%) use both, and 2.8 million (15.6%) do not take diabetes medications.
- > Self-monitoring of blood glucose (SMBG) is used to guide the day-to-day management of blood glucose

Prevalence

In 2004, an estimated 1,127,000 or 7.7% of New York residents had diagnosed diabetes, and an additional 451,000 were predicted to have undiagnosed type 2 diabetes.

Evidence

- Type 1 diabetes use as needed for improved glycemic control
- Type 2 No evidence of effect on clinical outcomes
 - HBA1c is not significantly lowered unless used in conjunction with intensive education or when baseline is >10%
 - Some indication of lower QoL and increased depression

Policy implications/levers

Consider "coverage limitation" for # of test strips for diet controlled and patients stabilized on oral meds. With newly diagnosed or with HBA1c>8% participating in structured program provide more strips until individual targets are reached or for a specified period of time pending review of need

Insulin Pumps

Category: Prior Authorization

Overview

Insulin pumps are therapeutic devices that continuously administer insulin to individuals with type 1 or type 2 diabetes. Pumps use short-acting insulin and deliver insulin at basal levels, as well as bolus amounts for meals.

Prevalence

In 2004, an estimated 1,127,000 or 7.7% of New York residents had diagnosed diabetes, and an additional 451,000 were predicted to have undiagnosed type 2 diabetes.

Evidence

- Type 1 Reduction in severe hypoglycemia. Compared to injections, some improvement in HbA1c control 0.1%-0.7% (0.5% clinically sig.). Increased abscesses, site reactions, and occlusions. Mixed results in children
- Type 2 Does not appear to improve glycemic control in adults. Does not appear to reduce severe hypoglycemia. No good quality evidence for children.

Policy Implications/Levers

- Insulin pumps are considerably more expensive than injections
- Consider "prior authorization" similar to CMS policy

Real-time Continuous Glucose Monitoring for Type 1 and Type 2 Diabetes Mellitus

Category: Never Event or Prior Authorization

Overview

- Continuous Glucose Monitoring (CGM) is a diagnostic technology for analyzing patterns of glucose fluctuation in diabetes
- Fingerstick glucose monitoring still required for therapeutic decisions (i.e., SMBG=self-monitoring of blood glucose) and for daily calibration

Prevalence

In 2004, an estimated 1,127,000 or 7.7% of New York residents had diagnosed diabetes, and an additional 451,000 were predicted to have undiagnosed type 2 diabetes.

Evidence

- Type 1 Clinical benefit from increased glycemic control uncertain. Insufficient evidence to determine effect on other health outcomes.
- > Type 2 Insufficient evidence to determine change in glucose control. Insufficient evidence of improved health outcomes.

Policy implications/levers

 Consider "never event" and/or "prior authorization" policies restricting use to one time or infrequent diagnostic needs in compliant patients with poor glucose control, frequent episodes of hypoglycemia or ketoacidosis, and/or unexplained fluctuations in glucose values before meals

Coronary Computed Tomographic Angiography Category: Coverage Limitation and/or Prior Authorization

Overview

Coronary computed tomographic angiography (CCTA) is an intermediate diagnostic test used to increase (if the test is positive) or decrease (if the test is negative) the probability of obstructive coronary artery disease (CAD) in patients presenting with chest pain.

Prevalence

- During 2006, heart disease caused 26% of all deaths, and is currently the leading cause of death in both men and women.
- In 2009, 785,000 US adults suffered from a heart attack, and 470,000 have had recurrent attacks.

Evidence

Supports use in patients with chest pain and normal ECG to rule out obstructive CAD so patients can be safely discharged into outpatient care.

Policy implications/levers

- Consider "coverage limitation" of CCTA exclusively to patients with low or intermediate pre-test probabilities of CAD to "rule out" obstructive CAD. Consider not covering for patients with CAD, without symptoms, with BMI > 40, rapid heart rate or other significant arrhythmia.
- Require 64 slice scanner and physician competence to perform CCTA

Functional Electrical Stimulators for Spinal Cord and Head Injury, Cerebral Palsy, and Upper Motor Neuron Diseases Category: Never Event

Overview

- Functional electrical stimulation (FES), which is the application of neuromuscular electrical stimulation (NMES) to activate portions of the neuromusculature, has been suggested as a means of restoring lost function and improving quality of life.
- To overcome the impairment caused by lesions in the brain or spinal cord, FES bypasses the central nervous system and directly stimulates intact motor nerves that innervate skeletal muscle.

Prevalence

- Traumatic Brain Injury (TBI): Approximately 5.3 million individuals who currently live with disabilities resulting from TBI. The incidence of TBI has been approximated to be 131 per 100,000 individuals. 18,000 New Yorkers are hospitalized each year due to TBI.
- Spinal Cord Injury (SCI): In 2007, the estimates of individuals in the US with both incomplete and complete SCI ranged from 227,080 to 300,938. There are approximately 11,000 new cases of SCI each year in the US.
- <u>Cerebral Palsy (CP):</u> In western nations, there are reported to be 3.6 CP cases per 1000 in 8-year-old children. More than 10,000 babies in the US are born with CP annually.
- Multiple Sclerosis (MS): In the US, approximately 400,000 individuals currently suffer from MS. The disease affects more than 2.5 million individuals worldwide.

Evidence

Insufficient evidence of efficacy for any of the conditions

Policy implications/levers

Consider "Never event" status for FES.

Vagus Nerve Stimulators for Depression

Category: Coverage Limitation

Overview

Vagus nerve stimulation (VNS) is a therapy advocated for treatment-resistant major depression and bipolar disorder in which electrical pulses are delivered to the cervical portion of the vagus nerve by an implanted generator

Prevalence

- Nationwide, the potential population of patients with "difficult-to-treat" or "treatment-resistant" depression where VNS might be used was estimated to be 200,000 in 2009.
- In New York, it is estimated that 7.8 percent of individuals have depressive symptoms, with 2.2 percent having been diagnosed as having a major depression.

Evidence

Does not support the use of VNS in patients with depression

Policy implications/levers

Consider "coverage limitation (never)" status for VNS as a treatment for depression.

Proton Beam Radiation

Category: Never Event

Overview

- Proton beam radiation is a type of particle therapy which uses a beam of protons to irradiate diseased tissue, most often in the treatment of cancer.
- Radiotherapy with charged particles can potentially deliver maximal doses while minimizing irradiation of surrounding tissues.

Prevalence

- As of December 2007 at least 61,800 patients have received particle beam radiotherapy around the world for various cancers and other diseases. The vast majority (approximately 54,000 or 87%) have received protons.
- As of 2009, seven centers in the US have facilities for particle (proton) irradiation, and at least four are under construction, at a cost ranging from \$100 to \$225 million each.

Evidence

No evidence of clinical benefit

Policy Implications/Levers

Consider "never event" for proton beam radiation, or consider reference pricing

Arthroscopic Surgery of the Knee for Osteoarthritis Category: Coverage Limitation

- Overview
 Osteoarthritis (OA) is a common orthopedic condition characterized by articular degeneration within a joint.
- Lavage and debridement are arthroscopic surgical procedures
 - Lavage aspirates intra-articular fluid and the washes out the joint.
 - Debridement involves removal of cartilage or meniscal fragments by variable methods including cartilage abrasion, excision of osteophytes and synovectomy.

Prevalence

- Clinical osteoarthritis is estimated to affect approximately 27 million people in the US and prevalence of OA of the knee may be as high as 37.4% of the population aged 60 and older.
- In 1998, there were 650,000 knee arthroscopy procedures in the US.

Evidence

No evidence of improvement in pain or function for osteoarthritis of the knee

Policy Implications/Levers

Consider "coverage limitation" for arthroscopy for primary diagnosis of osteoarthritis of the knee.

Terbutaline in Preterm Labor

Category: Coverage Limitation

Overview

Terbutaline sulfate is used, in select cases, to inhibit uterine contractions and prevent recurrent preterm labor. It can be administered orally, intravenously, or subcutaneously, and is FDA approved for the management of obstructive pulmonary disease.

Prevalence

- Preterm birth (<37 weeks gestation) is the largest contributor to neonatal morbidity and mortality.</p>
- In 2008, 12.01% (30,061) of total births (250,383) in New York State occurred at or prior to 36 weeks gestation.

Evidence

No evidence that continuous infusions lengthen gestation. Significant safety concerns (note FDA warning).

Policy implications/levers

 Consider "coverage limitation" for terbutaline (intravenous or subcutaneous delivery methods) for the management of preterm labor in pregnant women.



Tobacco Cessation Benefit

- Generous benefit for both pharmacotherapy and counseling.
- Estimated # of smokers (from CAHPS survey) almost 500,000.
- Using claims data (2009) only ~ 13% of smokers access the benefit.
 - 40% Initiative
- Is there a benefit design issue?



Costs of Inappropriate/Uncertain Coronary Angioplasty for Medicaid Patients in NYS



Coronary Heart Disease

- Heart Disease: No. 1 killer
- Coronary Heart Disease (CHD): most common type of heart disease-involves narrowing of coronary arteries due to plaque formation
- This narrowing can cause severe chest pain (angina) and can lead to heart attack and death when the blood supply to an artery is completely interrupted



Treatments for CHD

- Medical therapy
- Percutaneous coronary intervention (PCI, coronary angioplasty).
- Coronary artery bypass graft (CABG) surgery.
- PCI: Threading a catheter to the coronary arteries, inflating a balloon to widen the narrowed artery, and usually inserting a stent to hold the plaque against the artery wall.
- PCI is very effective for evolving heart attacks, but its value is less certain for patients with milder heart disease.

American College of Cardiology/American Heart Association (ACC/AHA) Appropriateness Criteria for PCI/CABG vs. Medical Therapy

- These criteria rate PCI and CABG surgery as appropriate, uncertain, or inappropriate as a function of severity of patients' heart disease, the results of their diagnostic tests and the amount of medical therapy they are taking.
- New York's Cardiac Registries (Cardiac Surgery Reporting System and Percutaneous Coronary Interventions Reporting System) can be used to determine which patients who underwent CABG surgery and PCI are appropriate for these procedures.



Appropriateness Findings

- CABG Surgery: appropriate 90% of the time
- PCI: For Medicaid patients from 7/1/09 through 12/31/10, 1,003 patients out of 3,785 could not be rated; of the remainder, 37% were appropriate, 51% were uncertain, and 12% were inappropriate.



Appropriateness Findings

THREE POSSIBLE SCENARIOS FOR DENIAL OF REIMBURSEMENT ARE AS FOLLOWS:

- (1) if all inappropriate cases were eliminated or not reimbursed.
- (2)if all inappropriate cases and all cases without non-invasive diagnostic tests/without adequate documentation of disease from diagnostic tests were eliminated or not reimbursed.
- (3)if all inappropriate cases, all cases without non-invasive diagnostic tests/without adequate documentation of disease from diagnostic tests, and all cases for which angioplasty had uncertain value were eliminated or not reimbursed.



Projected Annual Savings for each of the three scenarios

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At $20,000/PCI:
Scenario (1) $ 4,320,000
Scenario (2) $17,693,000
Scenario (3) $36,667,000
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Using a very conservative \$5,000 per PCI:

Scenario (1) \$1,080,000

Scenario (2) \$4,423,000

Scenario (3) \$9,167,000

Note: These savings estimates are preliminary and are subject to further review by DOH.



Medicaid Fee-for-Service Radiology Management Program



Program Background

- In 2000, health care expenditures for advanced imaging, such as CT scans, MRIs and nuclear medicine, rose substantially faster than more routine imaging services such as ultrasound and x-rays.
- In 2009, DOH issued an RFP for radiology management as part of efforts to modernize its fee-for-service Medicaid utilization management system.
- In 2011, DOH and its contractor began implementing and operating a radiology management program for prior authorization of advanced medical imaging studies for fee-for-service Medicaid beneficiaries.



Program Goals

- Access to quality care for Medicaid beneficiaries by ensuring that they receive the most clinically appropriate imaging studies.
- Application of nationally accepted, evidence-based clinical criteria to determine medical necessity of imaging studies.
- Educate prescribers regarding medically appropriate imaging studies.
- Manage the federally mandated benefit and achieve cost savings through elimination of inappropriate imaging utilization.



Communication and Roll Out

Early 2011:

- Target audiences included ordering practitioners, imaging providers and provider organizations.
- Education on new prior approval requirement.
- Provide all necessary materials to complete the prior approval process.

April-May 2011:

- Contractor began receiving and processing prior approval requests.
- After transition period, claim edits began denying payment if prior approval not obtained.



Key Aspects of Program

- Non-emergency outpatient only
- Fax or phone request
- Peer-to-peer consultation between contractor's radiologist and ordering practitioner if indicated
- Consideration of alternatives
- Website link: https://www.emedny.org/ProviderManuals/Radiology/index.aspx



Going Forward

- Contractor provides DOH with expert consultation on new advanced imaging technologies.
- Monitoring of utilization trends across regions, providers, and specialties.
- Ongoing outreach, education and feedback with providers on best practices.
- Alignment of radiology fees to the rest of the Medicare benchmarks in the Medicaid Physician fee schedule implemented on July 1, 2011.
- Utilization in June-August 2011 has decreased by onethird compared with year ago.



New Benefit Ideas Submitted

- Doula
- YMCA Diabetes Prevention Program
- Pharmacist reimbursement for Tobacco Cessation
- Nurse Family Partnership
- Gender Reassignment
- Counseling
- Breastfeeding Consultants



Draft Process for Benefit Reviews



Draft Process

- Internal and external group
- Clinical and payment analyses
- Transparency
- Process to evaluate impact of coverage decisions?
- Challenges
 - Resources
 - Evidence
 - Cost effectiveness analysis
 - Volume
 - Role of health plans



Next Steps

- Upcoming Meetings
- Agenda
- Materials/Information Needed