PANEL EXPERTS

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- George Koumas DDS Delta Dental
- Gordon Grundy MD AETNA

1

PRESENTATION GOALS

- To Define Medical Necessity
- To Demonstrate Policy Development
- To Illustrate Policy Applications

2

DEFINITION OF MEDICAL NECESSITY

- HIGHMARK MEDICAL POLICY Z-11
- BCBS ASSOCIATION POLICY DEFINITON
- MEDICARE ADVANTAGE MEDICAL POLICY Z-11

3

HIGHMARK

- **Medically Necessary or Medical Necessity** - means health care services or supplies that a provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing, or treating an illness, injury, disease, or its symptoms, and that are:in accordance with generally accepted standards of medical practice;clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; andnot primarily for the convenience of the patient or the provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

4

- For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Specialty Society recommendations, and the views of providers practicing in relevant clinical areas and any other relevant factors.

5

MEDICARE ADVANTAGE

- To determine whether a service or item is denied as “not medically necessary,” and whether the limitation of liability provision is applicable:
- The service or item must be otherwise covered; and,
- The service or item must be determined to be not reasonable and necessary for diagnosis or treatment of any kind of illness, injury, or medical condition (investigational or experimental) or for a particular case or for certain conditions.

6

EXAMPLES

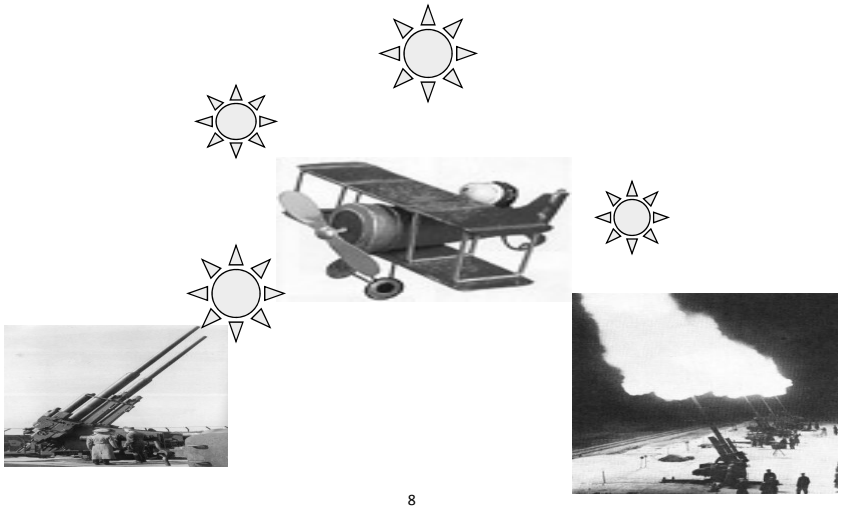
- 1. Intracranial Angioplasty experimental
- 2. Cold Therapy not medically necessary
- 3. Certain Neurophysiological Studies

- All documentation must be maintained in the medical records and be available upon request.
  Every page of the record must be legible and include appropriate patient indentification information (e.g., complete name, dates of service(s)). The record must include the physician or non-physician practitioner responsible for and providing the care of the patient.
  The submitted medical record should support the use of the selected ICD-9-CM code(s). The submitted CPT/HCPCS code should describe the service performed.
  The medical record should support the time spent in monitoring and correlate to the surgery being performed.

7

FLAK

When you receive flak, you know you are over the target!



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DAN BARNETT MD JD

THE EVIDENSE GATHERING PROCESS AND UTILIZATION OF TEC CRITERIA

9

BCBST Medical Policy Development Process

Extensive Evidence-Based Research conducted by Medical Policy Departments at Health Plans:

- Professionally published sources: TEC, Hayes, ECRI
- Large controlled, randomized studies published in peer-reviewed journals
- Consensus statements from Gold Standard organizations: National Guideline Clearinghouse, ADA, NIH, State Mandates

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Medical Technology Assessment Subcommittee (MTAS)

Technology Evaluation Criteria Utilized by BCBST

Consists of five aspects:

- Final approval received from appropriate government regulatory bodies (e.g., FDA)
- Scientific evidence permits conclusion about effect on health outcomes
- Improves net health outcome
- Must be as beneficial as established alternatives
- Improvement must be attainable outside the investigational setting

FRED HOLT MD JD

EXAMPLES OF POLICY APPLICATION

13

What Service for Prior Review?

High pmpm cost or cost trend → reasonable ROI

Elective

Abuse/overuse on med nec, investigational, bad, etc.

Manageable number of requests

Defensible authority behind coverage guidelines

Understandable for UR staff

Holt 1

Functional Endoscopic Sinus Surgery

Yearly cost trend 16-20% 2006-8 (doubles in 5 years)

Abuse: only 20% of sample met specialty guidelines

Defensible authority: modeled after AAO-HNS indicators

Requirements:

- History of sinusitis
- Demonstrated disease failing adequate medical management

Results: For discussion

Holt 2

Lumbar Spinal Fusion Surgery

Yearly national trend doubling every 3-4 years

Many done only for pain - failures, re-operations common

Defensible authority – cooperation with local, national spine surgeons and buy-in by ortho, neuro specialty societies (8)

Requirements:

- Imaging proof of visible disease correlating with pain
- Failed medical management, physical therapy for adequate time

Results: For discussion

Holt 3

GEORGE KOUMAS DDS

DENTAL POLICY PROVISIONS & APPLICATIONS

17

Medical/Dental Policy

- What procedures performed by dentists/physicians/surgeons can be clearly identified as dental or medical?
- Which plan should cover these procedures – dental or medical?
- Is there a clear company wide understanding of what constitutes medical procedures?
- Is it possible that claims processing can be confused as well as clinical review by dental/medical specialists regarding what is dental and what is medical?
- Has COB been appropriately set up to prevent overlap of coverage between medical and dental plans?
- Can there be a problem with double degree Oral and Maxillofacial Surgeons who only submit their medical or dental degrees to different plans?
- Who is writing/creating clinical policies for your company? Is it a single individual or by group/committee?

Examples of Medical Contract Language – Question- Who is looking at these claims?

- Services primarily provided for the care, treatment, removal or replacement of teeth or structures (e.g., root canals, fillings, crowns, bridges, dental prophylaxis, fluoride treatment, extensive dental restoration) directly supporting the teeth are non-covered services under the Medical-Surgical programs. (Blues)
- Dental services provided for the routine care, treatment, or replacement of teeth or structures (e.g., root canals, fillings, crowns, bridges, dental prophylaxis, fluoride treatment, and extensive dental restoration) or structures directly supporting the teeth are generally excluded from coverage under Aetna's medical plans, except under the limited circumstances outlined below.
  - Dental in nature vs medical in nature oral surgery
  - Medical services performed by a dentist
  - Treatment of the jaw
  - Facial trauma
  - Repair of cleft palate
  - TMJ/TMD
- Bone grafts to the maxilla (21210) and the mandible (21215) are eligible for payment only when performed due to unusual and extenuating circumstances, e.g., cancer or trauma. (Blues)
- Reconstruction of a dental ridge distorted as a result of removal of a tumor (including bone grafting and dental implants if necessary to stabilize a maxillofacial prosthesis such as an obturator).

Policy Provisions

- When Dental services are covered by Medical plans, is there a time limitation to complete services?
  - Ex: oral trauma/fractured teeth
  - What dental procedures are involved and eligible for payment?
  - What are the differences in payments between a medical and dental plan? What's the cost impact?

Policy Related to Claim Submissions

- COB
  - When submitting claims, are they submitted to dental or medical first
  - Is it procedure dependent?
  - What protective policies are in place in companies that offer both medical and dental plans?
  - Do the claims processing systems “speak” to each other?
    - Why is this important?
    - Is there a process defined by procedure for claims to be submitted?
    - How is this communicated to a dental or medical provider network?
    - How are the procedures identified?
      - Ex: treatment of osteomyelitis – medical or dental? Dependent up

EDWARD HUNSINGER MD

- A SIMPLE EXAMPLE WORTH 1.2 MILLION

22

Cooling and Compression Devices

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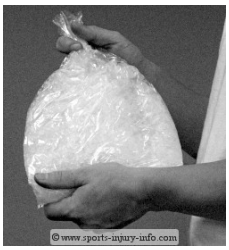

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23

Cold therapy cooling devices

Passive and active pump-controlled cooling and compression devices

ArcticFlow	Game Ready™	Nanotherm™
Cryo/Cuff™	Iceman	OPTI-ICE™
Polar Care Cub	BioCryo	Polar Care
AutoChill®	Arctic® Ice	Versa-Cool™
EBIce®	DeRoyal®	VitalWrap
		Vascutherm™

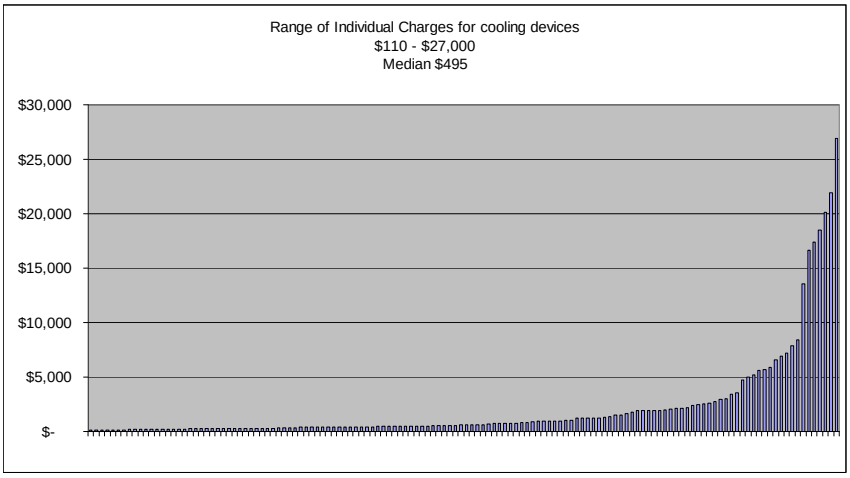
Post-op Surgeries of:
Ankle, Knee, Shoulder, Clavicle, Neck, L-Spine, Carpal Tunnel,

Non-op treatment of:
Palpatations, Toenail, Bunion, Femoral head,

24

They are expensive, but do they work better than ice packs?

HCPCS Codes E0218 & E0236



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Cigna Medical Coverage Policy Elements of a CP

1. Subject – Cryounits/Cooling Devices - #0314
2. Coverage Policy
   - Our conclusion on what we will cover and under what conditions
3. General Background
   - Discussion of technology, branded items on the market, explanation of what they are supposed to do
4. FDA position on the devices,
   - Approved for use applies to safety, not efficacy
5. Literature Review
   - Peer-reviewed studies on effectiveness in achieving stated goals, compared with current therapies
6. Summary
   - Conclusion on what the available evidence shows. Both effectiveness and cost compared with existing technology.
7. Coding/Billing Information
   - Those HCPCS and ICD-9CM codes that are billed for this technology
8. References
   - The sources of information that served as the basis of the decision.

26

CIGNA does not cover cold therapy units or cooling devices, including both passive and active pump-controlled cooling and compression devices, because they are considered convenience items and not medically necessary.

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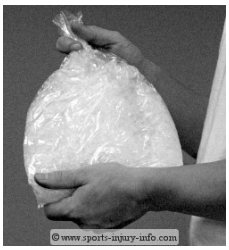

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27

28

The Role of Medical Coverage Policy Development in Combating Fraud & Abuse

Presented by: Gordon W. Grundy, MD, MBA
Medical Director
Special Investigations Unit

Framework of Medical Coverage Policy Development

- Focus on medical necessity and/or experimental and investigational status of medical services and technologies
- Supported by peer-reviewed medical literature, technology assessments, expert opinions, evidence-based guidelines and input from Federal agencies and specialty organizations
- Multiple sources for policy topics
- Formal comprehensive annual review and approval process with internal and external input and quality recommendations

30

Vertebral Axial Decompression

- Therapy for low back pain utilizing a motorized table to control disc decompression in treatment of herniated disc, degenerative disc, sciatica and radiculopathy
- Used in orthopedic and PT settings
- Multiple manufacturers and systems
- Misrepresentation using CPT codes 64722 or 97012 rather than the correct S9090
- Considered experimental and investigational based of lack of evidence in medical literature that therapy is an effective adjunct to conservative therapy for back pain

31

Parenteral Immunoglobulins (IVIG)

- FDA-approved for primary immunodeficiencies and many immune-mediated conditions
- Administered in therapy of many disorders for which medical literature and/or other sources do not support efficacy
- Very costly therapy for single use and when used at frequent intervals
- Misrepresentation of billing diagnosis to gain insurance coverage
- Coverage policy identifies medically necessary usages and specifies conditions for which IVIG therapy is experimental and investigational

32