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TREATMENT EXCLUSIONS & LIMITATIONS

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Treatment Exclusions and Limitations

Because of maximum benefit limitations, providers often find that the sickest patients may run out of insurance benefits. Although the patients are responsible for payment of medical treatment after coverage has been exhausted, such patients often have exhausted their personal resources during their illnesses. Before writing off such high-dollar treatment balances, it is important to appeal maximum benefit denials to determine whether all available benefits have been provided.

Maximum benefit audit requests

Sample Appeal Letter R, "Maximum Benefit Appeal – Request for Audit of Paid Claims," is a basic demand letter for clarification of available benefits This letter is useful for seeking how previous benefits were paid and how the maximum benefit limitation is worded in the policy or plan document. Often, a maximum benefit limitation will fall under one of the following four categories:

- **Lifetime maximum:** Most health insurance plans set a maximum benefit amount that will be provided for all covered services and supplies over the lifetime of the covered individual. A $1 million lifetime maximum is a common ceiling for health insurance coverage and should be clearly referenced in the policy or plan documents.

- **Procedure- and/or illness-specific maximum:** Some health insurance plans set a maximum benefit amount on services, supplies, and, occasionally, certain illnesses. State parity laws have lessened the prevalence of such limitations, but some still exist in exempted policies and plans.

- **Daily maximum:** Some health insurance plans limit the benefit that will be provided per day for a covered service. They may also limit the number of days that a service will be covered. These types of limits are generally used for services including mental and nervous disorders, skilled nursing facilities, and home health care.

- **Annual maximum:** Many health insurance plans limit the total benefit that will be provided

per year for covered services. If the annual maximum is applied, you may want to seek clarification regarding whether the annual maximum is determined by calendar year or some other date. This will allow you to determine whether full benefits were allowed for the time frame in question.

If there is a discrepancy in the information or if the patient believes that the calculation was made incorrectly, you may want to seek additional documentation related to the payments rendered. Your follow-up letter can request that the claim history be detailed to include all claims paid, the paid amount, and to whom the payment was released. Benefit calculation errors will sometimes occur because the carrier will total claim charge amounts instead of actual payments or will include duplicate claim submissions in the calculations.

If the applied maximum limitation is related to the diagnoses, you should seek clarification that all charges counted to the maximum are for the same diagnoses. Many policies and plans will have a set number of inpatient or outpatient covered days for mental illness and will accidentally include emergency or acute care days in the calculation when the acute care was for related health problems. This practice can be appealed, however, based on the fact that medical benefits are often calculated separately from mental illness benefits.

Experimental treatment appeals

Limitations on experimental treatment are almost universal in health insurance coverage. Similar to the discussion of the importance of the definition of medical necessity in Chapter 4, the definition of experimental treatment has changed over time and directly affects which treatments are covered and readily available and which are not covered. In the *American Medical Association Journal of Ethics* (2007, Vol. 9, 1), Attorney Lee Black identified the variety in experimental definitions and the effect on coverage in an article concerning experimental breast cancer treatment denials, stating:

> "The variety among insurance contract provision relating to coverage of experimental treatments is astounding. They range from very sparse language which offers little insight into what an insurer considers experimental to very detailed provisions. In

> general, the less detailed the language, the better the outcome for the patient who challenges a denial. This formula, however, is by no means foolproof. In some instances, even a definition of experimental that seems to allow for flexibility can be viewed by a court as sufficiently precise to preclude a challenge by the patient."
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> (Available online at *www.ama-assn.org/ama1/pub/upload/mm/384/0107-vm.pdf*.)

Appeals of experimental treatment should begin by seeking disclosure of the exact definition of *experimental treatment*. One of the specific components that may affect your appeal success is whether the definition references approval of independent medical authorities such as the U.S. Food and Drug Administration (FDA) or peer-reviewed medical journals. Unfortunately, many policies will state that the final authority for determining experimental care rests with the carrier or, in the case of group employee benefit plans, the plan fiduciary.

You will also need to provide detailed information about the service or medical supply, including any information you have regarding its efficacy and acceptance in the medical community. Some of the most commonly denied claims regarding experimental treatment exclusions are related to the following:

Off-label and/or nonformulary drugs: Medical providers often prescribe a drug for a diagnosis other than that for which the drug is FDA-approved. Plans develop formularies of approved drugs but often make case-by-case decisions regarding whether to cover nonformulary or off-label drug uses. A number of state laws require plans to cover nonformulary and off-label uses of a drug when there is medical evidence supporting the drug's efficacy. Appeals of off-label drug treatment should cite any such applicable laws as well as provide copies of any literature attesting to the drug's effectiveness. The drug manufacturer should be able to provide a list of articles and studies which discuss the drug's performance on off-label uses. The state laws generally recognize such medical authorities as *The American Medical Association Drug Evaluations*, *The United States Pharmacopeia Drug Information for the Consumer*, and *The American Hospital Formulary Service Drug Information*. Some laws also require coverage of off-label drug use as long as the drug is recognized as safe and effective in at least two articles from major peer-reviewed professional medical journals if contradictory published information is not available.

Clinical trials: Carriers frequently refuse to cover the costs of having their patients treated in clinical trials by defining *experimental* to include any treatment currently involved in clinical trials. At least 21 states, however, have passed mandates requiring some coverage for treatment extended as part of clinical trials. For many cancer patients, clinical trials offer state-of-the-art treatment. A number of the mandates extend only to cancer clinical trials but others are more far-reaching. You can research your state's clinical trial coverage at the Kaiser Family Foundation Web site, *www.statehealthfacts.org*.

New diagnostic tests or treatments: Medical advancements and technology have multiplied within the past decade and managed care organizations have taken numerous steps to control evaluation and reimbursement of new tests and treatments. Insurers once relied primarily on external standards, such as FDA approval and acceptance by specialty care groups, to determine experimental care. Experimental treatment assessment now incorporates a number of other sources including published technology assessments, evidence-based medicine, and independent medical experts who review published medical studies of the new test or procedure. The article "Payer Approval Is As Important As Regulatory Approval for New Medical Devices" encourages medical technology companies to routinely collect efficacy and cost-effectiveness data along with safety data in order to obtain quicker acceptance by payers. The author, Judith Hickey, described the pressures carriers face with the explosion of new products and procedures:

> "Medical product companies are being forced to demonstrate the value of healthcare technologies. This has resulted from pressure by—and on—insurers and managed care organizations to restrain premium increases by controlling costs within the healthcare system. While managed care organizations may receive the most publicity for their efforts in this regard, all insurers—from the self-insured employers to government programs—are dealing with these issues. In the future, cost control will become even more prevalent as an aging population begins to increasingly use medical technology advances, resulting in greater costs. In this context, it is important to be aware of and gather the data payers require from clinical trials. This audience will be a critical gatekeeper for the acceptance of new products."
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> (Source: *Regulatory Affairs Focus*, June 2003, Judith Hickey. Available online at *www.prgweb.com/pdf/03_Hickey_Payer_Approval.pdf*.)

Many insurers use the Technology Evaluation Center (TEC), founded by Blue Cross Blue Shield in 1985, for such assessments. The criteria used by TEC, available online at *www.bcbs.com/betterknowledge/tec/tec-criteria.html*, include these five points for making coverage recommendations:

1. The technology must have final approval from the appropriate governmental regulatory bodies.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes. Typically, the TEC board will conduct a search on Medline for all recent studies related to the technology under investigation.
3. The technology must improve the net health outcome.
4. The technology must be as beneficial as any established alternatives.
5. The improvement must be attainable outside investigational settings.

Medical devices and diagnostic tests and procedures that do not meet criteria such as these are often designated as experimental, but access to such treatment may still be granted on a case-by-case basis. In such appeals, each of the five TEC components should be addressed to clarify the most recent information related to the sought-after treatment. See Sample Appeal Letter S, "Lack of Precertification – Experimental/Invesigation Treatment," for an example of this type of letter.

Treatment caps: Justifying extended care

Some treatment, most notably occupational therapy, physical therapy, and chiropractic visits, are subject to insurance coverage treatment caps. Exceptions may be allowed on a case-by-case basis and medical billing professionals must be familiar with treatment cap appeals.

Medicare initiated a combined physical and speech-language pathology maximum of $1,740 in annual benefits as of January 1, 2001, matching the separate $1,740 cap for occupational services already in place. The Centers for Medicare & Medicaid Services (CMS) maintains a list of diagnoses that automatically qualify for additional care. (See *www.cms.hhs.gov/MLNMattersArticles/downloads/MM5478.pdf* for the table of qualifying diagnoses

and billing instructions.) In addition, CMS issued Transmittal 63 to provide clarification on rehabilitation billing and how specific assessment tools can be used to determine the need for extended treatment. The referenced tools include:

- National Outcomes Measurement System, by the American Speech-Language Hearing Association
- Patient Inquiry, by Focus on Therapeutic Outcomes, Inc.
- The Activity Measure for Post Acute Care, by Boston University
- OPTIMAL, by the American Physical Therapy Association

Section 220.3, "Documentation Requirements for Therapy Services," of Transmittal 63, states, in part, the following under Paragraph B, "Documentation Required":

"In documenting records, clinicians must be familiar with the requirements for covered and payable outpatient therapy services as described in the manuals. For example, the records should justify: . . .

- Services are of appropriate type, frequency, intensity, and duration for the individual needs of the patient.
- Documentation should establish the variables that influence the patient's condition, especially those factors that influence the clinician's decision to provide more services than are typical for the individual's condition.
- Clinicians and contractors shall determine typical services using published professional literature and professional guidelines. The fact that services are typically billed is not necessarily evidence that the services are typically appropriate. Services that exceed those typically billed should be carefully documented to justify their necessity, but are payable if the individual patient benefits from medically necessary services. Also, some services or episodes of treatment should be less than those typically billed, when the individual patient reached goals sooner than is typical.
- Documentation should establish through objective measurements that the patient is making progress toward goals. Note that regression and plateaus can happen during treatment. It is recommended that the reason for lack of progress be noted and the justification for continued treatment be documented if treatment continues after regression or plateaus.

Needs of the Patient. When a service is reasonable and necessary, the patient also needs the services. Contractors determine the patient's needs through knowledge of the individual patient's condition, and any complexities that impact that condition, as described in documentation (usually in the evaluation, re-evaluation, and Progress Report). Factors that contribute to needs vary, but in general they relate to factors such as the patient's diagnoses, complicating factors, age, severity, time since onset/acuity, self-efficacy/motivation, cognitive ability, prognosis, and medical, psychological and social stability. Patients who need therapy generally respond to therapy, so changes in objective and sometimes to subjective measures of improvement help establish the need for services. The use of scientific evidence, obtained from professional literature, and sequential measurements of the patient's condition during treatment is encouraged to support the potential for continue improvement that may justify the patient's need for therapy."

(Source: *www.cms.hhs.gov/Transmittals/Downloads/R63BP.pdf*)

Both Medicare and commercial coverage appeals will need to address the needs of the patient and be backed up by evidence-based medicine as cited earlier. When appealing, acknowledge the treatment cap and seek clarification to ensure that the therapy has not been counted against the cap which does not necessarily apply, such as counting physical therapy and occupational therapy together instead of allowing separate benefits. Make sure you address how the additional visits would allow the patient to meet the treatment goals for potential restoration outlined in the initial treatment plan.

Ensuring that the carrier is aware of dual-diagnosis issues

One of the major problems that arise with treatment caps is that the carrier may not recognize a dual diagnosis. Instead, the carrier looks at the primary diagnosis and applies the corresponding cap related to care for that diagnosis. In such situations, appeals should demand a more thorough review of how the secondary diagnosis affected the treatment plan. The following wording can be used to make this request:

> It is our understanding that your denial did not involve an in-depth review of the patient's medical record which documents treatment goals for two separate medical conditions. Instead, benefit availability was based on internally developed or published clinical review criteria related to the primary diagnosis only. It is our position that any clinical guideline

used for treatment assessment must address comorbidity treatment complications.

Medical guidelines employed for medical decision-making must be flexible and allow for deviations from the guideline in order to incorporate the patient's unique medical factors. Specifically, the following patient-specific variables should be addressed by the guideline and alternative treatment options discussed to make the criteria appropriate for the patient's age, sex, race, or ethnicity: comorbidities, socioeconomic considerations, treatment history, family medical history, treatment compliance record, potential side effects, allergies, and patient's concerns and goals regarding treatment options. Because there are so many patient-specific variables to assess, it is our position that the treating physician is in the best position to develop a dual-diagnosis treatment plan and has addressed these patient-specific variables in relation to the chosen acuity level in the patient medical record.

References

Black, L. 2007. "Experimental breast cancer treatments and health insurance coverage." *American Medical Association Journal of Ethics* 9 (1): 34–37.

Department of Health and Human Services, CMS Manual System. Section 220.3, "Documentation Requirements for Therapy Services," Transmittal 63. *www.cms.hhs.gov/Transmittals/Downloads/R63BP.pdf*.

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