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BENEFITS BULLETIN

REGULATORY UPDATES
CLAIM ISSUES

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DIRECT ACCESS TO PHYSICAL THERAPY

State Mandates - For several years, and especially since the Affordable Care Act was enacted, physical therapists' professional associations have been lobbying for laws allowing patients to self-refer themselves without a doctor's referral. This is usually referred to as "direct access." The arguments for direct access are: 1) physical therapists have the necessary clinical expertise to diagnose and treat musculoskeletal disorders; 2) patients will save money; and 3) patients can access treatment sooner.

These efforts have been very successful, and now all 50 states and the District of Columbia allow some form of direct access. The exact provisions vary from state to state:

- The majority of states limit direct-access to an initial evaluation along with a limited number of visits (e.g., twelve) before a doctor's referral is needed.
- 18 states allow for unlimited access absent a referral. Illinois recently became one of these unlimited-access states.

  Illinois Public Law 100-0897, enacted August 16, 2018, allows a physical therapist to evaluate, diagnose, design a treatment plan, and provide physical therapy (PT) services without a referral. There are no limits on the number of visits, except that the patient must be referred to a medical doctor if there is no measurable improvement within 15 days or after ten visits, whichever comes first, or if the patient has a reoccurrence after 30 days following the end of his course of treatment. The physical therapist is required to notify the patient's primary care physician within five days after starting PT.

18 states, including Illinois, allow almost unlimited access to physical therapy without a referral.

How Health Plans Are Responding - The state mandates do not require health plans to cover self-referred PT.

According to ATI Physical Therapy, a large PT provider:

- Blue Cross, Tricare, Medicaid, and Cigna require a physician's referral.
- United Healthcare and Aetna cover PT evaluations and initial therapy visits without referrals for patients with qualifying medical histories.
- Medicare continues to require a signed plan of care as a condition of payment and, in nearly all instances,

a prescription from a licensed physician, physician assistant, or nurse practitioner.

Reasons for Caution - Although the self-referral laws are based on good reasons, direct access could create problems for plan sponsors. For example:

- Physical therapists are not able to order x-rays or other tests, nor will they have access to the patient's complete medical records. This increases the possibility of misdiagnosis and/or failure to refer to the appropriate medical doctor.
- Utilization of PT services is already increasing, and in recent years many chiropractors have set up multi-disciplinary clinics that combine chiropractic, PT, massage and acupuncture services. According to the Coalition Against Insurance Fraud, combining chiropractic and other therapies "greatly multiplies opportunities for false billing, and can provide cover for schemes for each discipline."
- Removing the physician-referral requirement accelerates the blurring of the line between PT for sports and fitness, and PT for bona fide musculoskeletal disorders. PT clinics will have an increased financial incentive to find medical diagnoses for patients who are mostly interested in fitness.
- PT clinics are increasingly engaging in direct-to-consumer marketing, offering help to people who want to improve their body ergonomics, remain fit, or improve their mobility.

The state mandates do not require health plans to cover self-referred PT visits.

Reasons to Cover - Despite the cautions noted above, there are some good reasons to consider providing benefits for at least some self-referred PT:

- Patients won't have to wait for an appointment with their primary care physician or orthopedist.
- There will be no claim for the physician's visit.
- There will be pressure to cover placed on trustees and claims administrators from self-referring claimants. These patients will have been told by their PT provider that no referral is needed.

Recommendation - We recommend that plans follow the lead of the large insurers and CMS who are still requiring a physician's referral, and adopt a wait-and-see approach for the time being.

We recommend that trustees not amend their current provisions related to PT until the large insurers develop direct-access coverage guidelines.

NEW STAND-ALONE HRA'S

The Department of Health and Human Services, the Department of Labor and the Internal Revenue Service jointly issued a proposed rule on October 23, 2018 addressing employers' and plans' abilities to offer stand-alone health reimbursement accounts (HRAs) to their employees/participants.

HRAs provided through employer-sponsored health plans are currently required by the Affordable Care Act (ACA) to be integrated with traditional group health plans. In addition, these HRAs cannot reimburse participants for individual health insurance premiums. (Retiree-only plans are an exception to this requirement.)

The proposed rule permits two new types of HRAs:

- A stand-alone HRA that is integrated with individual health care coverage; and
- A stand-alone HRA that covers certain limited benefits.

1) Individual-Coverage HRAs

Proposed Rules - The proposed rules allow employer-sponsored plans to provide HRAs that are integrated with individual health plans and cover individual health insurance premiums if the following conditions are met:

- All covered persons (including dependents) must be enrolled in an individual health insurance plan while covered by the HRA. The individual plan can be an exchange plan, but does not have to be.
  - The HRA sponsor must implement reasonable procedures to verify that covered persons are enrolled in the individual coverage.
  - The individual plan does not have to meet any particular requirement, other than it cannot cover limited benefits only (dental/vision, etc.).
- If the plan offers an HRA option to any class of employees, it cannot also offer a traditional group health plan to the same class of employees.

  Examples of allowable classes are:
  - Full-time employees
  - Part-time employees
  - Seasonal employees
  - Employees covered by a collective bargaining agreement
  - Employees who have not satisfied the plan's waiting period
  - Employees under age 25
  - Employees in different ACA rating (underwriting) areas

  Health status cannot be a factor when dividing employees into classes, nor can employees be in different classes based on whether they are salaried or hourly.
- The same amount and the same conditions must apply to all employees within the class.
  - Different dollar amounts cannot be provided within a class except on the basis of age or family size to account for higher premiums on the individual market.

  - The HRA can, however, be provided only for retirees who had a minimum number of years of service.

- Participants must be permitted to opt out of the HRA at least annually, and upon termination of employment.

- Participants must be notified on an annual basis that enrolling in the individual-coverage HRA makes them ineligible for the ACA's premium tax credit, that the coverage is not subject to ERISA, and several other details.

Individual-Coverage HRAs and the Employer Mandate - In general, a stand-alone individual-coverage HRA will be considered an "offer of coverage" sufficient to avoid the employer penalties, however, determining whether or not the HRA meets the affordability standard complicates the matter. Therefore, in separate guidance (Notice 2018-88), the IRS requested comments on several proposed safe harbors that would help large employers ensure that their HRAs satisfy the ACA's employer mandate. The safe harbor proposals are not explained in this bulletin because an employer contributing to a multiemployer plan pursuant to collective bargaining agreement or participation agreement is exempt from having to determine affordability under a special exemption that is still in effect.

2) Limited Benefit HRAs

The second proposed HRA arrangement would allow the HRA to reimburse participants up to $1,800 per year for "limited excepted benefits" such as dental and/or vision insurance, or long-term care insurance. A participant would be eligible to participate in this type of HRA regardless of whether he or she has any other health care coverage.

The $1,800 limit will be adjusted annually for inflation.

The proposed rules contain a requirement that the HRA not be an integral part of the regular plan, but another provision elsewhere states that participants must also be offered a traditional group plan. The final rules may clarify this contradiction.

What This Means for Multiemployer Plans

Although aimed at small employers, these rules could provide new alternatives for multiemployer plans. It is not anticipated that trustees will move their current participants from traditional plans to individual insurance plans. However, trustees may find that an individual-coverage HRA might be an attractive option for retirees or previously uncovered classes, such as part-time employees.

The limited-benefit HRA option may also prove popular, especially for plans that do not currently offer dental and/or vision coverage.

Rules Could Change - The regulations described above are not final and are, therefore, subject to change. In their final form, the rules would become effective January 1, 2020 at the earliest.

To Read the Proposed Rule - The proposed rule was published in the October 29, 2018 Federal Register. It is available at https://www.federalregister.gov/documents/2018/10/29/2018-23183/health-reimbursement-arrangements-and-other-account-based-group-health-plans.

NEW PREVENTIVE SERVICES

The Affordable Care Act (ACA) requires non-grandfathered plans to cover a variety of preventative care services at 100% (in-network). The types of preventive services subject to this requirement are based on recommendations made by organizations such as the U.S. Preventative Services Task Force, Bright Futures, and the Advisory Committee on Immunization Practices. When a new service or supply is added to the recommendations, plan coverage should start on the first day of plan year following one year from recommendation date.

All the recently added recommendations are shown in the following chart:

Service/Supply	Eff. Date
Preeclampsia screening and monitoring for pregnant women*	First PY on/after 4/1/18
Vision screening for children ages 3-5 years to detect amblyopia**	First PY on/after 9/1/18
Skin cancer behavioral counseling for fair-skinned children 6 mos. to 24 yrs. & parents of young children	First PY on/after 3/1/19
Exercise interventions to prevent falls (65+ adults in group facilities)***	First PY on/after 4/1/19
Osteoporosis screening with bone measurement testing for 1) women 65+; and 2) post-menopausal women under 65 who are at risk for osteoporosis****	First PY on/after 6/1/19
Cervical cytology testing for women: 1) every 3 years for ages 21+; or 2) every 5 years with hrHPV testing	First PY on/after 8/1/19
Syphilis testing during pregnancy	First PY on/after 9/1/19
Obesity screening, and counseling for adults with 30+ BMI	First PY on/after 9/1/19
Screening for unhealthy alcohol use for adults 18+ and pregnant women, and brief behavioral counseling interventions	First PY on/after 11/1/19
PY=plan year	
**Since this involves blood pressure screening only, the services could be included in OB case fee.*	
***Vision acuity exams are already covered for ages <5.*	
****Facility should provide as part of service.*	
*****Osteoporosis recommendation is a non-substantial revision to prior recommendation.*	

MICHIGAN HICA TAX REPEALED

Michigan's Health Insurance Claims Assessment (HICA) tax has been repealed effective October 1, 2018.

HICA is being replaced with a tax payable by insurers, not self-funded plans.

REVISITING COB RULES ON ADULT CHILDREN

If a plan follows the most recent NAIC Coordination of Benefits guidelines, then the following order of payment applies to an adult child, i.e., a child not living with his parents, and not covered by a court decree:

- If the child has his own coverage plus coverage under a parent's plan, then the non-dependent/dependent rule applies, and the child's plan is primary.
- If the child is covered under his spouse's plan and also covered under his parent's plan, then the longer/shorter rule applies.

TESTING PATIENTS ON PAIN MEDS

Many doctors are requiring frequent urine drug tests (UDTs) for their patients taking pain medications, especially opioids, on a long-term basis. The testing is performed even for patients who are at low risk for abusing those drugs. Some physicians are also ordering expensive immunoassay tests that look for other substances and quantify the amount of all substances tested.

There is a strong consensus among medical professionals that periodic urine tests are valuable for patients taking strong pain medications on a long-term basis. (See "CDC Guideline for Prescribing Opioids for Chronic Pain," *Recommendations and Reports,* March 18, 2016.) However, there is still no standard for the numbers of drug tests a chronic pain-management patient should undergo per year. Government agencies, medical societies and the large insurers currently use varying guidelines.

Recommendation - We recommend that administrators ask their utilization review organizations for guidelines. For example, some plans allow no more than four UDTs per year for patients at low risk for opioid abuse. More frequent tests, and quantitative tests are covered only if there is evidence that the patient is at a higher risk for abusing the drugs, or if a UDT indicates the presence of non-prescribed drugs.

Best practice is to describe the plan's drug testing guidelines in the SPD or in an SMM.

This does not apply to patients in drug rehab programs.

DISCLOSING HOW R&C IS DETERMINED

Whenever a plan denies part of a charge because it is in excess of the reasonable and customary (R&C) amount, the Explanation of Benefits (EOB) is required to disclose the methodology used to determine the R&C amount. In a recent case, the US District Court for Southern Michigan ruled that since the defendant health plan's Explanation of Benefits did not state the plan's methodology as required by ERISA's claim procedures, then R&C had to be interpreted to mean the prevailing market rate (*Zack v. McLaren Health*). A "prevailing" rate can be much higher than a "reasonable" rate.

If your plan still bases out-of-network claims on actual R&C data, you should make sure the EOB reason messages disclose the methodology used, preferably using language from the plan's SPD.

Plans that base out-of-network reimbursement on a percentage of Medicare's allowable amount should be denying excess charges as being in excess of the "allowable amount," not for being over R&C. If, for example, the plan allows up to 130% of Medicare, the EOB message will state that the denied amount is "in excess of 130% of Medicare allowable."

TMS FOR DEPRESSION

Transcranial magnetic stimulation/TMS (or rTMS, "r" for repetitive) is becoming a common treatment for depression. It is a noninvasive procedure using magnetic fields to stimulate nerve cells in the brain. TMS is claimed to improve symptoms of depression for patients whose symptoms are resistant to other types of therapy. It is usually administered three-to-five times per week for several weeks in a row (for a total of about 30 sessions).

TMS is popular since it is safe, side-effect free, and performed in physicians' offices. It is also heavily advertised.

While the effectiveness of TMS is still being studied and debated, the major insurers have found that the evidence is adequate enough to cover TMS for major depression that is unresponsive to anti-depressant therapy.

Claims payors should follow the advice of their medical review organizations if TMS claims are received for conditions other than major depression. At this time, TMS appears to be investigational for all other indications, but ongoing studies could affect that determination.

GENE THERAPY

The US Food and Drug Administration (FDA) has approved a handful of genetic therapy products for treating diseases such as hemophilia, congenital blindness and AIDS/HIV.

These very expensive products are designed to enter and manipulate the patient's cells via a vector, for example a genetically modified virus, in order to reverse the effects of the disease.

Luxturna® is the most well known of these therapies. It has been approved to treat patients with genetic retinal dystrophy, a disease that can cause complete blindness in some patients. Luxturna works by delivering a normal copy of the affected gene directly to

retinal cells by way of a naturally occurring adenovirus that has been modified using recombinant DNA techniques. The cost of one course of treatment is $850,000.

The number of people who can benefit from Luxturna or one of the other FDA-approved gene therapies is currently very small. But additional products are in the development and testing pipeline.

Because gene testing products require administration by a medical professional, many of these will be medical, not pharmacy, claims.

PCORI FEES ENDING

PCORI fees do not apply to plan years ending after Sept. 30, 2019. For calendar year plans, the final PCORI fees will be paid in July 2019 for the 2018 calendar year. Many plans with mid-year plan years will need to make a payment in July 2020. For example, the final PCORI payment for a plan with a June 1 plan year will be in July 2020 for its June 2018-May 2019 plan year.

The amount used to calculate the PCORI fee for plan years ending Oct. 1, 2018, through Sept. 30, 2019 is $2.45 per person.

HPID DEATH NOTICE COMING

Remember the unique health plan identifier (HPID) and other entity identifier (OEID)? The HPID was a unique 10-digit number mandated under HIPAA electronic standard transaction rules. Third-party administrators were identified by OEIDs. These IDs were to be used on all electronic claims transactions.

Phased-in implementation was supposed to start in 2014. At the last minute, however, HHS delayed the requirement indefinitely due to complaints about the difficult and confusing registration process and the fact that other types of unique identifiers were already serving the purpose.

On December 19, 2018 the US Department of Health and Human Services (HHS) issued a notice of proposed rulemaking that would finally rescind the requirements to apply for and use these identifiers.