For example, the program covers diabetic reagent test strips. It makes no difference whether the manufacturer of the product has entered into a rebate agreement with the federal government. Vaccines are exempt from the rebate program. Vaccines are covered regardless of the rebate status of the manufacturer.

Federal Drug Efficacy Study Implementation Program

Enactment of the *Federal Food, Drug, and Cosmetics Act of 1938*, established the requirement that a manufacturer prove the safety of a drug before it could be marketed in the United States. In 1962, this act was amended to require that drugs sold in the United States be regulated more closely. All new drugs must be shown by adequate studies to be both safe and effective before being marketed. The Drug Efficacy Study Implementation (DESI) Program was established to monitor these studies.

Federal law prohibits state Medicaid agencies from reimbursing for less than effective (LTE) Drug Efficacy Study Implementation (DESI) drugs, or any drug that the federal government has determined to be identical, related, or similar (IRS) to a less than effective drug. *Appendix B* of this chapter provides a complete list of these drugs.

DESI drugs are listed in this chapter by name, manufacturer, dosage form, and NDC. These products are not reimbursed by the IHCP under any circumstances. Updates to the DESI list are sent to providers quarterly.

Mandatory Substitution

The 590 Program, Traditional Medicaid, and Hoosier Healthwise (Prime*Step* Primary Care Case Management (PCCM) delivery system) do not reimburse for brand name drugs when a comparable generic is available, unless the prescribing physician has indicated **brand medically necessary (BMN)**. *Indiana Code Drugs: Generic Drugs, IC 16-42-22-10* mandates substitution of a generic equivalent drug for a prescribed brand name drug unless the prescribing provider properly indicates BMN in the prescriber's own handwriting. Pharmacists should refer to the existing statute for complete information about the mandatory substitution provision of the program. A copy of the applicable statute is provided in this chapter for reference. *Mandatory substitution does not apply to Hoosier Healthwise Package C members.*

Prior Authorization

The following services provided by a pharmacy require prior authorization (PA):

- **590 Program Members:** All services provided to 590 Program members for billed amounts greater than $500 per procedure
- **Nutritional Supplements:** Nutritional supplements, food supplements, and infant formula. Refer to *405 IAC 5-24-9* for additional information.
- **Medical Supplies:** Incontinence supplies. Refer to *405 IAC 5-19-1* for additional information. Incontinence supplies include such items as underpads, incontinence briefs and liners, diapers, and disposable diapers.

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- **Durable Medical Equipment:** *Medical Supply and Durable Medical Equipment* entries in this chapter and *405 IAC 5-19-6* provide additional information.
- **Brand Medically Necessary:** *IC 16-42-22-10* provides additional information.

Refer to *405 IAC 5-19-2* and *405 IAC 5-19-6* for the definition of DME. If a determination cannot be made between medical supplies and DME, contact the Customer Assistance Unit for clarification.

Billing Prior Authorized Services

Providers should follow the procedures below when billing for a service that requires PA:

- The *Indiana Prior Review and Authorization Request Decision Form* is sent to the member and the requesting provider, noting the authorization decision for the specific item. The PA number is found on this form. *Chapter 6* provides additional information. This form is available on the IHCP Web site at www.indianamedicaid.com.
- Information from the *Indiana Prior Review and Authorization Request Decision Form*, the approved NDC code, or procedure code, is entered on the *IFSSA Drug Claim Form*, or the *HCFA-1500* claim form, in the NDC number, or procedure code, field:
  - If an assigned code is 11 characters in length, it **must** be billed on the *IFSSA Drug Claim Form*.
  - If an assigned procedure code is five characters in length, it **must** be billed on the *HCFA-1500* claim form.
  - If not enrolled as a DME and medical supply provider and not able to bill on the *HCFA-1500* claim form, and an approved Indiana Prior Review and Authorization Request Decision Form is received for a service having a five-character procedure code, contact the HCE Prior Authorization Unit. The code needs to be changed to the appropriate 11-character procedure code. The provider may be required to send a System Update Request to the Prior Authorization Unit depending on the complexity of the issue. Refer to *Chapter 6* for additional information.

Smoking Cessation Treatment Services

This information is also located in *Chapter 8* of this manual.

Coverage and Billing Procedures

Coverage of smoking cessation treatment services is for dates of service on or after October 27, 1999.

Eligible Providers and Practitioners

Practitioners eligible to provide smoking cessation treatment counseling services, but not currently enrolled as IHCP providers, should complete a provider enrollment application. The application is available on the IHCP Web site at www.indianamedicaid.com or can be requested from **EDS Customer Assistance at (317) 655-3240** in the Indianapolis local area or **1-800-577-1278**. Eligible practitioners, such as pharmacists who work for or own IHCP-enrolled pharmacies,

maintain documentation in their usual manner. Examples of documentation that should be maintained by the provider of the service include, but are not limited to:

- Written order for the service
- Date the service is rendered
- Amount of time used for the training session
- General content of the training session
- Units of service billed
- Charge amount
- Pertinent patient history
- Clinical data
- Practitioner notes from the training sessions

Legend Drug Coverage

The program covers all Food and Drug Administration (FDA)-approved legend drugs, from rebating manufacturers **except** the following:

- Anorectics or any agent used to promote weight loss
- Drugs when prescribed solely or primarily for cosmetic purposes
- Fertility enhancement drugs
- Topical minoxidil preparations

Non-Legend Drug Coverage and Over-the-Counter Formulary

An OTC Drug Formulary has been established, and a non-legend drug must be on the OTC Drug Formulary to be a covered service. This allows for the use of medically necessary OTC or non-legend drug products whenever possible, rather than prescribing more expensive legend drugs. The OTC Drug Formulary impacts only *over-the-counter drugs*. A revised formulary is based on recommendations made by the Indiana Drug Utilization Review (DUR) Board. The complete OTC Drug Formulary is located in *Appendix D* of this chapter.

Pharmacy providers in particular should be aware of the IHCP OTC Drug Formulary, as dispensing and claim filing practices are affected by the revision of the formulary in the following ways:

- Reimbursement is not available for OTC Drug Formulary products from non-rebating manufacturers. System modifications to Indiana*AIM* ensure that claims for OTC drugs not listed on the OTC Drug Formulary are denied. This increases the defensibility of IHCP claims data used to obtain federally-mandated rebates from participating drug manufacturers.
- The formulary is *drug, strength*, and *dosage-form* specific to the extent noted on the formulary. For example, if a drug is listed on the formulary only as a 10 mg tablet, and other strengths exist, only the 10 mg tablet is reimbursable.