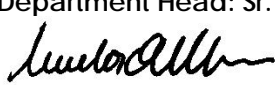
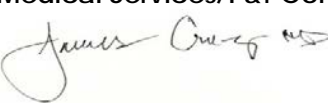


Policy Title: Evaluation of New Technologies		POLICY #: 70.2.30	
		Line of business: ALL	
Department Name: Utilization Management	Original Date 2/06	Effective Date 5/19	Revision Date 12/18
Department Head: Sr. Director, UM 			Date: 3/21
Medical Services/P&T Committee: (If Applicable) PHP CMO 			Date: 3/21

PURPOSE

To evaluate and address the inclusion of new medical technologies and new application of existing medical technologies, as part of the defined benefit plan. This indicates medical procedures, covered behavioral health procedures, pharmaceuticals and devices.

POLICY

Blue Shield of California Promise (Blue Shield Promise) recognizes the importance of evaluating new technology or the new application of existing technology as part of the benefit or on a case by case basis. The goal of the evaluation process is to ensure that members have equitable access to safe and effective care.

Blue Shield Promise primarily contracts with governmental agencies for the provision of health care services to those enrolled in government health programs. As such, under Federal and State Law, Blue Shield Promise is required to cover those services as defined by the governmental entity. As new technology is developed or applications of existing technology are discovered, governmental agencies have a process of evaluation of existing technology for a specifically requested service on a case by case basis as described below.

PROCEDURE

The Medical Services Committee is responsible for oversight of the evaluation processes described below. The Board of Directors is responsible for final approval of the coverage of a new technology or the new application of an existing technology.

Prior to a decision to implement, a new technology or the new application of an existing technology government agencies usually provide a public comment period. As part of this process, Blue Shield Promise will offer either testimony or written comment to the appropriate agency in scientific sources, information from appropriate government regulatory bodies, and input from relevant specialists or professionals who have expertise in the technology. If adopted by the governmental agency, the new technology or application of an existing technology will be incorporated into the benefit plan.

Evaluation of new technology and the new application of existing technology for inclusion in Blue Shield Promise's benefit plan include the evaluation of the following:

- Medical procedures
- Behavioral healthcare procedures
- Pharmaceuticals
- Devices

A case-based decision to cover a specifically requested service that involves a new technology, or the new application of an existing technology will follow much the same process. Prior to the decision to cover the requested service, the Chief Medical Officer, as a representative of the Medical Services Committee, will conduct a review of current literature from published scientific sources, obtain information from appropriate government regulatory bodies, or seek input from relevant specialists or professionals who have expertise in the technology, prior to making a decision to authorize the requested service. Consideration will be given to whether or not the requested service is an Experimental or Investigative procedure. (See UM P&P 70.2.29 E & I Review).

Blue Shield Promise shall involve the behavioral healthcare practitioner in the decision-making process of evaluating new technology and new application of existing technology, if applicable.

If the requested service is approved, the case will be forwarded to the Medical Services Committee for review and possible revision of medical necessity guidelines or procedures. The Medical Services committee may also decide to request a formal evaluation by governmental agencies for possible inclusion of the new technology or new application of existing technology into the benefit plan to ensure that members have equitable access to safe and effective care.

The Board of Directors will be informed and has final approval over any recommendations made by the Medical Services Committee to a governmental agency regarding the evaluation of new technology or the new application of existing technology.

In the case of pharmaceutical, the Pharmacy, the Pharmacy & Therapeutics (P&T) Committee is responsible for assessing the appropriateness of including new medications or new applications of existing medications into the plan formulary. The P & T Committee will follow much the same process as described above. It will review information from appropriate government regulatory bodies, review information from published scientific sources, and seek input from relevant specialists or professionals with expertise with the medication as part of its' evaluation process. P&T Committee recommendations will be presented to the Board of Directors for consideration and to government entities who are considering the new medications or new application of an existing medication for inclusion into the formulary.

On a case by case basis, the Chief Medical Officer, as a representative of P&T Committee, will conduct a review of current literature from published scientific sources, obtain information from appropriate government regulatory bodies, or seek input from relevant specialists or professionals who have expertise with the medication, prior to making a decision to authorize the requested medication. Consideration will be given to whether or not the requested service is an Experimental or Investigative procedure (SEE UM P&P 70.2.29 E&I Review).

If the requested medication is approved, the case will be forwarded to the P&T Committee for review and possible revision of medical necessity guidelines or procedures. The P&T Committee may also decide to request a formal evaluation by governmental agencies for possible inclusion

of the new medication or new application of an existing medication into the plan benefit formulary.

Factors to be considered when evaluating the limitation of adding a new technology or the new application of existing technology, pharmaceutical or making a case by case decision include:

- The technology must improve outcomes
- The technology must be beneficial as any established alternatives
- The improvement must be attainable outside the investigational setting
- The technology must have final approval from the appropriate government regulatory bodies

If a new medical technology, new application or existing medical technology, procedure, pharmaceutical and/or device is included as a Blue Shield Promise Health Plan benefit, all Plan Partner's and/or Providers will be notified in writing within 30 days of the decision by the applicable Blue Shield Promise Health Plan committee so that the change can be included in the Member Handbook(s) (Evidence of Coverage(s) regarding the new benefit

REFERENCES

NCQA Standards and Guidelines
Title 42, CFR Sections 417.101 and 438.210