

Medical Coverage Policies

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Single-Patient Drug Trials

EFFECTIVE DATE	11/17/2009	LAST UPDATED	10/19/2010
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Description:

CPT® Category III code 0130T was created for the purpose of single-patient clinical trials used as a prognostic tool in community practice. Single patient drug trials are used to guide treatment decisions by evaluating drug effectiveness and tolerance in individual patients who serve as their own controls.¹ It is believed single-patient drug trials would produce the information needed to assist primary care physicians in the management of some chronic diseases (e.g., allergic rhinitis, chronic heartburn, or osteoarthritis pain). Typically, clinicians have resorted to trial-and-error such as telling patients to use 1 drug for 1 week, another for the next week, and then report which drug works best for them.

A standardized methodology was developed that can be used routinely in clinical practice to optimize treatment decisions on an individual basis. A Personalized Medicine Test (PMT) kit, to be prescribed by the physician for patients with a chronic disease, and data management and reporting system were created in order to determine the clinical outcome (i.e., the patient's response) to two chronic care drugs at a time.

Medical Criteria:

Not applicable.

Policy:

The single-patient trial test kits investigation of FDA approved chronic care drugs is not covered as BCBSRI does not reimburse for services performed by a pharmacist.

Coverage:

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Coding:

The following code is non-covered:

0130T

Also Known as:

Opt-e-scrip

Publications:

Provider Update, January 2010

Provider Update, December 2010

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