Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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**Description:**

Transanal endoscopic microsurgery (TEMS) is a surgical procedure to resect rectal tumors not typically removed through the anus. An operating proctoscope, insufflation and magnified stereoscopic views are used.
TRANSANAL ENDOSCOPIC MICROSURGERY (TEMS) (cont.)

Criteria:

➢ Transanal Endoscopic Microsurgery (TEMS) is considered medically necessary for the treatment of ANY of the following:

1. Benign rectal tumors (adenomas)
2. Rectal carcinoma with documentation of ALL of the following:
   - < 1/3 the circumference of the rectum
   - < 3 cm in size
   - Clear margins
   - Mobile, non-fixed
   - Within 8 cm of anal verge
   - T1 only
   - Well to moderately differentiated (G1 or G2)
   - No evidence of lymphadenopathy on pretreatment imaging

➢ Transanal Endoscopic Microsurgery (TEMS) for all other indications not previously listed, is considered experimental or investigational based upon:

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
4. Insufficient evidence to support improvement outside the investigational setting.

These conditions include, but are not limited to:

- Rectal strictures
- Rectal fistulae
- Rectal abscesses
TRANSANAL ENDOSCOPIC MICROSURGERY (TEMS) (cont.)

Resources:


TRANSANAL ENDOSCOPIC MICROSURGERY (TEMS) (cont.)

Resources: (cont.)


FDA 510K Summary for Transanal Endoscopic Microsurgery (TEM) Combination System and Instrument Set:

- FDA-approved indication: To provide access to the rectal cavity and accessible part of the lower sigmoid colon using a stereo and/or monocular endoscope under gas tight conditions for the excision of polyps and/or the removal of tumors that have been previously staged.