MetroPlus Health Plan

Policy and Procedure

Title: Remicade Biosmiliar Step Therapy	Division: Medical Management Department: Utilization Management
Approval Date: 10/26/2018	LOB: Medicare
Effective Date: 1/1/2019	Policy Number: UM-MP241
Review Date:	Cross Reference Number:
Retired Date:	Page 1 of 5

1. POLICY DESCRIPTION:

Step Therapy Requirement for Remicade (J1745); trial with biosimilar Inflectra (Q5103) or Renflexis (Q5104).

2. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

3. DEFINITIONS:

Biosimilar is a biologic medication that is developed to be highly similar and clinical equvilant to an existing biologic medication.

4. POLICY:

Remicade (J1745) will be considered medically necessary for beneficiaries/members with when all of the following criteria are met.

1. Documented failure with Inflectra or Renflexis
2. Dose and frequency is in in accordance with the FDA label, recognized compendia (for off-label uses) or as documented within the Local Coverage Determination (LCD) for Infliximab, Infliximab-dyyb, Infliximab-abda.
3. Documentation requirements are provided as listed within the Local Coverage Determination (LCD) for Infliximab, Infliximab-dyyb, Infliximab-abda.

5. LIMITATIONS/ EXCLUSIONS:

This policy is only applicable to new starts. Members already on therapy with Remicade will not be subjected to this step therapy requirement. MetroPlus will utilize a 6-month lookback period.

Additional limitations and exclusions consistent with those listed within the Local Coverage Determination (LCD) for Infliximab, Infliximab-dyyb, Infliximab-abda.

6. APPLICABLE PROCEDURE CODES:

CPT	Description
J1745	Injection, infliximab, excludes biosimilar, 10 mg
Q5103	Injection, filgrastim-sndz, biosimilar, (Zarxio), 1 mcg

Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

7. APPLICABLE DIAGNOSIS CODES:

CODE	Description
K50.00 - K50.919	Crohn's disease of small intestine without complications - Crohn's disease, unspecified, with unspecified complications
K51.00 - K51.919	Ulcerative (chronic) pancolitis without complications - Ulcerative colitis, unspecified with unspecified complications
L40.0 - L40.9	Psoriasis vulgaris - Psoriasis, unspecified
M05.00 - M05.9	Felty's syndrome, unspecified site - Rheumatoid arthritis with rheumatoid factor, unspecified
M06.00 - M06.39	Rheumatoid arthritis without rheumatoid factor, unspecified site - Rheumatoid nodule, multiple sites
M06.80 - M06.9	Other specified rheumatoid arthritis, unspecified site - Rheumatoid arthritis, unspecified
M08.00 - M08.29	Unspecified juvenile rheumatoid arthritis of unspecified site - Juvenile rheumatoid arthritis with systemic onset, multiple sites
M08.3	Juvenile rheumatoid polyarthritis (seronegative)

M08.80 - M08.99	Other juvenile arthritis, unspecified site - Juvenile arthritis, unspecified, multiple sites
M45.0 - M45.9	Ankylosing spondylitis of multiple sites in spine - Ankylosing spondylitis of unspecified sites in spine
M48.8X1 - M48.9	Other specified spondylopathies, occipito-atlanto-axial region - Spondylopathy, unspecified
M65.9	Synovitis and tenosynovitis, unspecified
A18.54	Tuberculous iridocyclitis
D86.0 - D86.9	Sarcoidosis of lung - Sarcoidosis, unspecified
H20.00 - H20.9	Unspecified acute and subacute iridocyclitis - Unspecified iridocyclitis
H44.111 - H44.119	Panuveitis, right eye - Panuveitis, unspecified eye
H44.131 - H44.139	Sympathetic uveitis, right eye - Sympathetic uveitis, unspecified eye
K52.1	Toxic gastroenteritis and colitis
L73.2	Hidradenitis suppurativa
M30.1	Polyarteritis with lung involvement [Churg-Strauss]
M31.30	Wegener's granulomatosis without renal involvement
M31.31	Wegener's granulomatosis with renal involvement
M31.4	Aortic arch syndrome [Takayasu]
M35.2	Behcet's disease
L88	Pyoderma gangrenosum

8. REFERENCES:

1. Local Coverage Determination (LCD) for Infliximab, Infliximab-dyyb, Infliximab-abda (e.g., Remicade™, Inflectra™, Renflexis) – Related to LCD L33394 (A52423)) via: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52423&ver=43&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&KeyWord=Infliximab&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&

REVISION LOG:

REVISIONS	DATE

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Approved: Date:	Approved: Date:
Bruce Sosler, MD Clinical Medical Director	Talya Schwartz, MD Chief Medical Officer

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty

that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.