Ridaura (auranofin)
Policy Number: C14523-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
9/1/2018	9/25/2019	9/25/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J3490 (NOC)-Unclassified drugs	RxPA	Q4 2019 20191030C14523-A

PRODUCTS AFFECTED:
Ridaura (auranofin)

DRUG CLASS:
Gold Compounds

ROUTE OF ADMINISTRATION:
Oral

PLACE OF SERVICE:
Retail Pharmacy
The recommendation is that medications in this policy will be for pharmacy benefit coverage and patient self-administered

AVAILABLE DOSAGE FORMS:
Ridaura Cap 3MG

FDA-APPROVED USES:
indicated in the management of adults with active classical or definite rheumatoid arthritis (ARA criteria) who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of full doses of one or more nonsteroidal anti-inflammatory drugs. RIDAURA should be added to a comprehensive baseline program, including nondrug therapies.

COMPENDIAL APPROVED OFF-LABELED USES:

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: Rheumatoid Arthritis

REQUIRED MEDICAL INFORMATION:
A. RHEUMATOID ARTHRITIS:

1. Documentation of CBC with differential, platelet count, urinalysis, and renal and liver function tests should be performed prior to RIDAURA (auranofin) therapy to establish a baseline and identify any preexisting conditions
   AND
2. Insufficient therapeutic response to, or are intolerant of, an adequate trial of full doses of one or more nonsteroidal anti-inflammatory drugs (NSAIDS examples: Meloxicam, Diclofenac, Naproxen, or Celecoxib)
   AND

3. Failure of TWO formulary DMARDs (DMARDs examples: Methotrexate, Leflunomide, Hydroxychloroquine)

DURATION OF APPROVAL:
Initial authorization: 90 days, Continuation of Therapy: 180 days

QUANTITY:
6 mg daily (qty 60 capsules/30 days)—Maximum: 9 mg daily (qty 90 capsules/30 days)

PRESCRIBER REQUIREMENTS:
Rheumatology (requesting physician should be experienced in chrysotherapy)

AGE RESTRICTIONS:
18 years of age and older

GENDER:
Male and female

CONTINUATION OF THERAPY:
A. RHEUMATOID ARTHRITIS:
1. CBC with differential, platelet count and urinalysis should then be monitored at least monthly; other parameters should be monitored as appropriate.
   AND
2. Monitor signs of possible gold toxicity include fall in hemoglobin, leukopenia below 4,000 WBC/cu mm, granulocytes below 1,500/cu mm, decrease in platelets below 150,000/cu mm, proteinuria, hematuria, pruritus, rash, stomatitis or persistent diarrhea.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of RIDAURA are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. RIDAURA (auranofin) is contraindicated in patients with a history of any of the following gold-induced disorders: ana phylactic reactions, necrotizing enterocolitis, pulmonary fibrosis, exfoliative dermatitis, bone marrow aplasia or other severe hematologic disorders. The safety of concomitant use of RIDAURA (auranofin) with injectable gold, hydroxychloroquine, penicillamine, immunosuppressive agents (e.g., cyclophosphamide, azathioprine, or methotrexate) or high doses of corticosteroids has not been established.

OTHER SPECIAL CONSIDERATIONS:
Hematologic Reactions: Blood dyscrasias including leukopenia, granulocytopenia, thrombocytopenia and aplastic anemia have all been reported as reactions to injectable gold and RIDAURA. These reactions may occur separately or in combination at any-time during treatment. Because they have potentially serious consequences, blood dyscrasias should be constantly watched for through regular monitoring (at least monthly) of the formed elements of the blood throughout treatment.

BACKGROUND:
None

APPENDIX:
None

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. Riduara [package insert]. San Diego, CA: Prometheus Laboratories, Inc. January 2011
2. Singh, J., Saag, K., Bridges, S., Akl, E., Bannuru, R., & Sullivan, M. et al. (2015). 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research, 68(1), 1-25. doi: 10.1002/acr.22783