Orencia® (Abatacept) Injection for Intravenous Infusion

Policy Number: 2020D0039N
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Instructions for Use

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Coverage Rationale

See Benefit Considerations

This policy refers to Orencia (abatacept) injection for intravenous infusion. Orencia (abatacept) for self-administered subcutaneous injection is obtained under the pharmacy benefit.

Orencia is proven for the treatment of polyarticular juvenile idiopathic arthritis when all of the following criteria are met:
- For initial therapy, all of the following:
  - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA); and
  - Orencia is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for polyarticular juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule):
    - 10mg/kg every 4 weeks for patients weighing <75kg
    - 1,000mg every 4 weeks for patients weighing ≥75kg

    and
  - Patient is not receiving Orencia in combination with either of the following:
    - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

    and
  - Initial authorization is for no more than 12 months
- For continuation of therapy, all of the following:
  - Patient has previously received Orencia injection for intravenous infusion; and
  - Documentation of positive clinical response; and
  - Orencia is dosed according to FDA labeled dosing for polyarticular juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule):
    - 10mg/kg every 4 weeks for patients weighing <75kg
    - 1,000mg every 4 weeks for patients weighing ≥75kg

    and
  - Patient is not receiving Orencia in combination with either of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

and
- Authorization is for no more than 12 months

Orencia is medically necessary for the treatment of polyarticular juvenile idiopathic arthritis when all of the following criteria are met:
- For initial therapy, all of the following:
  - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA); and
  - Orencia is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for polyarticular juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule):
    - 10mg/kg every 4 weeks for patients weighing <75kg
    - 1,000mg every 4 weeks for patients weighing ≥75kg

    and
  - Patient is not receiving Orencia in combination with either of the following:
    - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

    and
  - Prescribed by or in consultation with a rheumatologist; and
  - Initial authorization is for no more than 12 months
- For continuation of therapy, all of the following:
  - Patient has previously received Orencia injection for intravenous infusion; and
  - Documentation of positive clinical response; and
  - Orencia is dosed according to FDA labeled dosing for polyarticular juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule):
    - 10mg/kg every 4 weeks for patients weighing <75kg
    - 1,000mg every 4 weeks for patients weighing ≥75kg

    and
  - Patient is not receiving Orencia in combination with either of the following:
    - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

    and
  - Prescribed by or in consultation with a rheumatologist; and
  - Authorization is for no more than 12 months

Orencia is proven for the treatment of rheumatoid arthritis when all of the following criteria are met:
- For initial therapy, all of the following:
  - Diagnosis of moderately to severely active rheumatoid arthritis (RA); and

    and
  - Orencia is initiated and titrated according to FDA labeled dosing for rheumatoid arthritis up to a maximum of (or equivalent dose and interval schedule):
    - 500mg every 4 weeks for patients weighing <60kg
    - 750mg every 4 weeks for patients weighing 60kg to 100kg
    - 1,000mg every 4 weeks for patients weighing >100kg

    and
  - Patient is not receiving Orencia in combination with either of the following:
    - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

    and
  - Initial authorization is for no more than 12 months
- For continuation of therapy, all of the following:
  - Patient has previously received Orencia injection for intravenous infusion; and

- Documentation of positive clinical response; and
- Orencia is dosed according to FDA labeled dosing for rheumatoid arthritis up to a maximum of (or equivalent dose and interval schedule):
  - 500mg every 4 weeks for patients weighing <60kg
  - 750mg every 4 weeks for patients weighing 60kg to 100kg
  - 1,000mg every 4 weeks for patients weighing >100kg

  and
- Patient is not receiving Orencia in combination with either of the following:
  - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
  - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

  and
- Authorization is for no more than 12 months

Orencia is medically necessary for the treatment of rheumatoid arthritis when all of the following criteria are met:

- For initial therapy, all of the following:
  - Diagnosis of moderately to severely active rheumatoid arthritis (RA); and
  - One of the following:
    - History of failure intolerance to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced; or
    - Patient is currently on Orencia;

    and
  - Orencia is initiated and titrated according to FDA labeled dosing for rheumatoid arthritis up to a maximum of (or equivalent dose and interval schedule):
    - 500mg every 4 weeks for patients weighing <60kg
    - 750mg every 4 weeks for patients weighing 60kg to 100kg
    - 1,000mg every 4 weeks for patients weighing >100kg

    and
  - Patient is not receiving Orencia in combination with either of the following:
    - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

    and
  - Prescribed by or in consultation with a rheumatologist; and
  - Initial authorization is for no more than 12 months
- For continuation of therapy, all of the following:
  - Patient has previously received Orencia injection for intravenous infusion; and
  - Documentation of positive clinical response; and
  - Orencia is dosed according to FDA labeled dosing for rheumatoid arthritis up to a maximum of (or equivalent dose and interval schedule):
    - 500mg every 4 weeks for patients weighing <60kg
    - 750mg every 4 weeks for patients weighing 60kg to 100kg
    - 1,000mg every 4 weeks for patients weighing >100kg

    and
  - Patient is not receiving Orencia in combination with either of the following:
    - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

    and
  - Prescribed by or in consultation with a rheumatologist; and
  - Authorization is for no more than 12 months

Orencia is proven for the treatment of psoriatic arthritis when all of the following criteria are met:

- For initial therapy, all of the following:
  - Diagnosis of active psoriatic arthritis (PsA); and
  - Orencia is initiated and titrated according to FDA labeled dosing for psoriatic arthritis up to a maximum of (or equivalent dose and interval schedule):

        - 500mg every 4 weeks for patients weighing <60kg
        - 750mg every 4 weeks for patients weighing 60kg to 100kg
        - 1,000mg every 4 weeks for patients weighing >100kg

      and
    - Patient is not receiving Orencia in combination with any of the following:
        - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
        - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]
        - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

      and
    - Initial authorization is for no more than 12 months
- For continuation of therapy, all of the following:
    - Patient has previously received Orencia injection for intravenous infusion; and
    - Documentation of a positive clinical response; and
    - Orencia is dosed according to FDA labeled dosing for psoriatic arthritis up to a maximum of (or equivalent dose and interval schedule):
        - 500mg every 4 weeks for patients weighing <60kg
        - 750mg every 4 weeks for patients weighing 60kg to 100kg
        - 1,000mg every 4 weeks for patients weighing >100kg

      and
    - Patient is not receiving Orencia in combination with any of the following:
        - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
        - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]
        - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

      and
    - Authorization is for no more than 12 months

Orencia is medically necessary for the treatment of psoriatic arthritis when all of the following criteria are met:
- For initial therapy, all of the following:
    - Diagnosis of active psoriatic arthritis (PsA); and
    - One of the following
        - History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced; or
        - Patient is currently on Orencia;

      and
    - Orencia is initiated and titrated according to FDA labeled dosing for psoriatic arthritis up to a maximum of (or equivalent dose and interval schedule):
        - 500mg every 4 weeks for patients weighing <60kg
        - 750mg every 4 weeks for patients weighing 60kg to 100kg
        - 1,000mg every 4 weeks for patients weighing >100kg

      and
    - Patient is not receiving Orencia in combination with any of the following:
        - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
        - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]
        - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

      and
    - Prescribed by or in consultation with one of the following:
        - Rheumatologist
        - Dermatologist

      and
    - Initial authorization is for no more than 12 months
- For continuation of therapy, all of the following:
    - Patient has previously received Orencia injection for intravenous infusion; and
    - Documentation of a positive clinical response; and
    - Orencia is dosed according to FDA labeled dosing for psoriatic arthritis up to a maximum of (or equivalent dose and interval schedule):

- 500mg every 4 weeks for patients weighing <60kg
- 750mg every 4 weeks for patients weighing 60kg to 100kg
- 1,000mg every 4 weeks for patients weighing >100kg

and
- Patient is not receiving Orencia in combination with any of the following:
  - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
  - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]
  - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

  and
- Prescribed by or in consultation with one of the following:
  - Rheumatologist
  - Dermatologist

  and
- Authorization is for no more than 12 months

Orencia is proven and/or medically necessary for the treatment of chronic graft-versus-host disease (GVHD) when all of the following criteria are met:
- For initial therapy, all of the following:
  - Diagnosis of steroid-refractory chronic GVHD; and
  - One of the following:
    - Patient is receiving Orencia in combination with systemic corticosteroids
    - Patient is intolerant to systemic corticosteroid therapy

    and
  - Initial authorization is for no more than 12 months
- For continuation of therapy, all of the following:
  - Documentation of positive clinical response; and
  - Patient continues to experience chronic GVHD; and
  - One of the following:
    - Patient is receiving Orencia in combination with systemic corticosteroids
    - Patient is intolerant to systemic corticosteroid therapy
    - Patient has been successfully tapered off of corticosteroid therapy

    and
  - Authorization is for no more than 12 months

Orencia is proven and/or medically necessary for the treatment of immune checkpoint inhibitor-related toxicities when all of the following criteria are met:[67]
- Patient has recently received checkpoint inhibitor therapy [e.g., Keytruda (Pembrolizumab), Opdivo (Nivolumab)];and
- Diagnosis of severe (G3) or life threatening (G4) immunotherapy-related myocarditis, pericarditis, arrhythmias, or impaired ventricular function, or conduction abnormalities; and
- No improvement of toxicity within 24 hours of starting pulse-dose methylprednisolone; and
- History of failure, contraindication, or intolerance to infliximab (e.g., Inflectra, Remicade); and
- Authorization is for no more than 4 doses

Orencia is unproven and not medically necessary for the treatment of:
- Multiple sclerosis
- Systemic lupus erythematosus
- Uveitis associated with Behçet's disease

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J0129	Injection, abatacept, 10 mg

Diagnosis Code	Description
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft versus host disease: (acute exacerbation of a chronic GVHD status, or acute manifestation of a preexisting GVHD associated condition)
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.54	Psoriatic juvenile arthropathy
L40.59	Other psoriatic arthropathy
M05.00	Felty's syndrome, unspecified site
M05.011	Felty's syndrome, right shoulder
M05.012	Felty's syndrome, left shoulder
M05.019	Felty's syndrome, unspecified shoulder
M05.021	Felty's syndrome, right elbow
M05.022	Felty's syndrome, left elbow
M05.029	Felty's syndrome, unspecified elbow
M05.031	Felty's syndrome, right wrist
M05.032	Felty's syndrome, left wrist
M05.039	Felty's syndrome, unspecified wrist
M05.041	Felty's syndrome, right hand
M05.042	Felty's syndrome, left hand
M05.049	Felty's syndrome, unspecified hand
M05.051	Felty's syndrome, right hip
M05.052	Felty's syndrome, left hip
M05.059	Felty's syndrome, unspecified hip
M05.061	Felty's syndrome, right knee
M05.062	Felty's syndrome, left knee
M05.069	Felty's syndrome, unspecified knee
M05.071	Felty's syndrome, right ankle and foot
M05.072	Felty's syndrome, left ankle and foot
M05.079	Felty's syndrome, unspecified ankle and foot
M05.09	Felty's syndrome, multiple sites
M05.20	Rheumatoid vasculitis with rheumatoid arthritis of unspecified site
M05.211	Rheumatoid vasculitis with rheumatoid arthritis of right shoulder
M05.212	Rheumatoid vasculitis with rheumatoid arthritis of left shoulder
M05.219	Rheumatoid vasculitis with rheumatoid arthritis of unspecified shoulder
M05.221	Rheumatoid vasculitis with rheumatoid arthritis of right elbow
M05.222	Rheumatoid vasculitis with rheumatoid arthritis of left elbow
M05.229	Rheumatoid vasculitis with rheumatoid arthritis of unspecified elbow

Diagnosis Code	Description
M05.231	Rheumatoid vasculitis with rheumatoid arthritis of right wrist
M05.232	Rheumatoid vasculitis with rheumatoid arthritis of left wrist
M05.239	Rheumatoid vasculitis with rheumatoid arthritis of unspecified wrist
M05.241	Rheumatoid vasculitis with rheumatoid arthritis of right hand
M05.242	Rheumatoid vasculitis with rheumatoid arthritis of left hand
M05.249	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hand
M05.251	Rheumatoid vasculitis with rheumatoid arthritis of right hip
M05.252	Rheumatoid vasculitis with rheumatoid arthritis of left hip
M05.259	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hip
M05.261	Rheumatoid vasculitis with rheumatoid arthritis of right knee
M05.262	Rheumatoid vasculitis with rheumatoid arthritis of left knee
M05.269	Rheumatoid vasculitis with rheumatoid arthritis of unspecified knee
M05.271	Rheumatoid vasculitis with rheumatoid arthritis of right ankle and foot
M05.272	Rheumatoid vasculitis with rheumatoid arthritis of left ankle and foot
M05.279	Rheumatoid vasculitis with rheumatoid arthritis of unspecified ankle and foot
M05.29	Rheumatoid vasculitis with rheumatoid arthritis of multiple sites
M05.30	Rheumatoid heart disease with rheumatoid arthritis of unspecified site
M05.311	Rheumatoid heart disease with rheumatoid arthritis of right shoulder
M05.312	Rheumatoid heart disease with rheumatoid arthritis of left shoulder
M05.319	Rheumatoid heart disease with rheumatoid arthritis of unspecified shoulder
M05.321	Rheumatoid heart disease with rheumatoid arthritis of right elbow
M05.322	Rheumatoid heart disease with rheumatoid arthritis of left elbow
M05.329	Rheumatoid heart disease with rheumatoid arthritis of unspecified elbow
M05.331	Rheumatoid heart disease with rheumatoid arthritis of right wrist
M05.332	Rheumatoid heart disease with rheumatoid arthritis of left wrist
M05.339	Rheumatoid heart disease with rheumatoid arthritis of unspecified wrist
M05.341	Rheumatoid heart disease with rheumatoid arthritis of right hand
M05.342	Rheumatoid heart disease with rheumatoid arthritis of left hand
M05.349	Rheumatoid heart disease with rheumatoid arthritis of unspecified hand
M05.351	Rheumatoid heart disease with rheumatoid arthritis of right hip
M05.352	Rheumatoid heart disease with rheumatoid arthritis of left hip
M05.359	Rheumatoid heart disease with rheumatoid arthritis of unspecified hip
M05.361	Rheumatoid heart disease with rheumatoid arthritis of right knee
M05.362	Rheumatoid heart disease with rheumatoid arthritis of left knee
M05.369	Rheumatoid heart disease with rheumatoid arthritis of unspecified knee
M05.371	Rheumatoid heart disease with rheumatoid arthritis of right ankle and foot
M05.372	Rheumatoid heart disease with rheumatoid arthritis of left ankle and foot
M05.379	Rheumatoid heart disease with rheumatoid arthritis of unspecified ankle and foot
M05.39	Rheumatoid heart disease with rheumatoid arthritis of multiple sites
M05.40	Rheumatoid myopathy with rheumatoid arthritis of unspecified site
M05.411	Rheumatoid myopathy with rheumatoid arthritis of right shoulder
M05.412	Rheumatoid myopathy with rheumatoid arthritis of left shoulder

Diagnosis Code	Description
M05.419	Rheumatoid myopathy with rheumatoid arthritis of unspecified shoulder
M05.421	Rheumatoid myopathy with rheumatoid arthritis of right elbow
M05.422	Rheumatoid myopathy with rheumatoid arthritis of left elbow
M05.429	Rheumatoid myopathy with rheumatoid arthritis of unspecified elbow
M05.431	Rheumatoid myopathy with rheumatoid arthritis of right wrist
M05.432	Rheumatoid myopathy with rheumatoid arthritis of left wrist
M05.439	Rheumatoid myopathy with rheumatoid arthritis of unspecified wrist
M05.441	Rheumatoid myopathy with rheumatoid arthritis of right hand
M05.442	Rheumatoid myopathy with rheumatoid arthritis of left hand
M05.449	Rheumatoid myopathy with rheumatoid arthritis of unspecified hand
M05.451	Rheumatoid myopathy with rheumatoid arthritis of right hip
M05.452	Rheumatoid myopathy with rheumatoid arthritis of left hip
M05.459	Rheumatoid myopathy with rheumatoid arthritis of unspecified hip
M05.461	Rheumatoid myopathy with rheumatoid arthritis of right knee
M05.462	Rheumatoid myopathy with rheumatoid arthritis of left knee
M05.469	Rheumatoid myopathy with rheumatoid arthritis of unspecified knee
M05.471	Rheumatoid myopathy with rheumatoid arthritis of right ankle and foot
M05.472	Rheumatoid myopathy with rheumatoid arthritis of left ankle and foot
M05.479	Rheumatoid myopathy with rheumatoid arthritis of unspecified ankle and foot
M05.49	Rheumatoid myopathy with rheumatoid arthritis of multiple sites
M05.50	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified site
M05.511	Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder
M05.512	Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder
M05.519	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified shoulder
M05.521	Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow
M05.522	Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow
M05.529	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified elbow
M05.531	Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist
M05.532	Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist
M05.539	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified wrist
M05.541	Rheumatoid polyneuropathy with rheumatoid arthritis of right hand
M05.542	Rheumatoid polyneuropathy with rheumatoid arthritis of left hand
M05.549	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hand
M05.551	Rheumatoid polyneuropathy with rheumatoid arthritis of right hip
M05.552	Rheumatoid polyneuropathy with rheumatoid arthritis of left hip
M05.559	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hip
M05.561	Rheumatoid polyneuropathy with rheumatoid arthritis of right knee
M05.562	Rheumatoid polyneuropathy with rheumatoid arthritis of left knee
M05.569	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified knee
M05.571	Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot
M05.572	Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot
M05.579	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified ankle and foot

Diagnosis Code	Description
M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites
M05.60	Rheumatoid arthritis of unspecified site with involvement of other organs and systems
M05.611	Rheumatoid arthritis of right shoulder with involvement of other organs and systems
M05.612	Rheumatoid arthritis of left shoulder with involvement of other organs and systems
M05.619	Rheumatoid arthritis of unspecified shoulder with involvement of other organs and systems
M05.621	Rheumatoid arthritis of right elbow with involvement of other organs and systems
M05.622	Rheumatoid arthritis of left elbow with involvement of other organs and systems
M05.629	Rheumatoid arthritis of unspecified elbow with involvement of other organs and systems
M05.631	Rheumatoid arthritis of right wrist with involvement of other organs and systems
M05.632	Rheumatoid arthritis of left wrist with involvement of other organs and systems
M05.639	Rheumatoid arthritis of unspecified wrist with involvement of other organs and systems
M05.641	Rheumatoid arthritis of right hand with involvement of other organs and systems
M05.642	Rheumatoid arthritis of left hand with involvement of other organs and systems
M05.649	Rheumatoid arthritis of unspecified hand with involvement of other organs and systems
M05.651	Rheumatoid arthritis of right hip with involvement of other organs and systems
M05.652	Rheumatoid arthritis of left hip with involvement of other organs and systems
M05.659	Rheumatoid arthritis of unspecified hip with involvement of other organs and systems
M05.661	Rheumatoid arthritis of right knee with involvement of other organs and systems
M05.662	Rheumatoid arthritis of left knee with involvement of other organs and systems
M05.669	Rheumatoid arthritis of unspecified knee with involvement of other organs and systems
M05.671	Rheumatoid arthritis of right ankle and foot with involvement of other organs and systems
M05.672	Rheumatoid arthritis of left ankle and foot with involvement of other organs and systems
M05.679	Rheumatoid arthritis of unspecified ankle and foot with involvement of other organs and systems
M05.69	Rheumatoid arthritis of multiple sites with involvement of other organs and systems
M05.70	Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement
M05.711	Rheumatoid arthritis with rheumatoid factor of right shoulder without organ or systems involvement
M05.712	Rheumatoid arthritis with rheumatoid factor of left shoulder without organ or systems involvement
M05.719	Rheumatoid arthritis with rheumatoid factor of unspecified shoulder without organ or systems involvement
M05.721	Rheumatoid arthritis with rheumatoid factor of right elbow without organ or systems involvement
M05.722	Rheumatoid arthritis with rheumatoid factor of left elbow without organ or systems involvement
M05.729	Rheumatoid arthritis with rheumatoid factor of unspecified elbow without organ or systems involvement
M05.731	Rheumatoid arthritis with rheumatoid factor of right wrist without organ or systems involvement
M05.732	Rheumatoid arthritis with rheumatoid factor of left wrist without organ or systems involvement
M05.739	Rheumatoid arthritis with rheumatoid factor of unspecified wrist without organ or systems involvement
M05.741	Rheumatoid arthritis with rheumatoid factor of right hand without organ or systems involvement
M05.742	Rheumatoid arthritis with rheumatoid factor of left hand without organ or systems involvement
M05.749	Rheumatoid arthritis with rheumatoid factor of unspecified hand without organ or systems involvement
M05.751	Rheumatoid arthritis with rheumatoid factor of right hip without organ or systems involvement
M05.752	Rheumatoid arthritis with rheumatoid factor of left hip without organ or systems involvement
M05.759	Rheumatoid arthritis with rheumatoid factor of unspecified hip without organ or systems involvement
M05.761	Rheumatoid arthritis with rheumatoid factor of right knee without organ or systems involvement

Diagnosis Code	Description
M05.762	Rheumatoid arthritis with rheumatoid factor of left knee without organ or systems involvement
M05.769	Rheumatoid arthritis with rheumatoid factor of unspecified knee without organ or systems involvement
M05.771	Rheumatoid arthritis with rheumatoid factor of right ankle and foot without organ or systems involvement
M05.772	Rheumatoid arthritis with rheumatoid factor of left ankle and foot without organ or systems involvement
M05.779	Rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot without organ or systems involvement
M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
M05.7A	Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement
M05.80	Other rheumatoid arthritis with rheumatoid factor of unspecified site
M05.811	Other rheumatoid arthritis with rheumatoid factor of right shoulder
M05.812	Other rheumatoid arthritis with rheumatoid factor of left shoulder
M05.819	Other rheumatoid arthritis with rheumatoid factor of unspecified shoulder
M05.821	Other rheumatoid arthritis with rheumatoid factor of right elbow
M05.822	Other rheumatoid arthritis with rheumatoid factor of left elbow
M05.829	Other rheumatoid arthritis with rheumatoid factor of unspecified elbow
M05.831	Other rheumatoid arthritis with rheumatoid factor of right wrist
M05.832	Other rheumatoid arthritis with rheumatoid factor of left wrist
M05.839	Other rheumatoid arthritis with rheumatoid factor of unspecified wrist
M05.841	Other rheumatoid arthritis with rheumatoid factor of right hand
M05.842	Other rheumatoid arthritis with rheumatoid factor of left hand
M05.849	Other rheumatoid arthritis with rheumatoid factor of unspecified hand
M05.851	Other rheumatoid arthritis with rheumatoid factor of right hip
M05.852	Other rheumatoid arthritis with rheumatoid factor of left hip
M05.859	Other rheumatoid arthritis with rheumatoid factor of unspecified hip
M05.861	Other rheumatoid arthritis with rheumatoid factor of right knee
M05.862	Other rheumatoid arthritis with rheumatoid factor of left knee
M05.869	Other rheumatoid arthritis with rheumatoid factor of unspecified knee
M05.871	Other rheumatoid arthritis with rheumatoid factor of right ankle and foot
M05.872	Other rheumatoid arthritis with rheumatoid factor of left ankle and foot
M05.879	Other rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot
M05.89	Other rheumatoid arthritis with rheumatoid factor of multiple sites
M05.8A	Other rheumatoid arthritis with rheumatoid factor of other specified site
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified
M06.00	Rheumatoid arthritis without rheumatoid factor, unspecified site
M06.011	Rheumatoid arthritis without rheumatoid factor, right shoulder
M06.012	Rheumatoid arthritis without rheumatoid factor, left shoulder
M06.019	Rheumatoid arthritis without rheumatoid factor, unspecified shoulder
M06.021	Rheumatoid arthritis without rheumatoid factor, right elbow
M06.022	Rheumatoid arthritis without rheumatoid factor, left elbow
M06.029	Rheumatoid arthritis without rheumatoid factor, unspecified elbow
M06.031	Rheumatoid arthritis without rheumatoid factor, right wrist
M06.032	Rheumatoid arthritis without rheumatoid factor, left wrist

Diagnosis Code	Description
M06.039	Rheumatoid arthritis without rheumatoid factor, unspecified wrist
M06.041	Rheumatoid arthritis without rheumatoid factor, right hand
M06.042	Rheumatoid arthritis without rheumatoid factor, left hand
M06.049	Rheumatoid arthritis without rheumatoid factor, unspecified hand
M06.051	Rheumatoid arthritis without rheumatoid factor, right hip
M06.052	Rheumatoid arthritis without rheumatoid factor, left hip
M06.059	Rheumatoid arthritis without rheumatoid factor, unspecified hip
M06.061	Rheumatoid arthritis without rheumatoid factor, right knee
M06.062	Rheumatoid arthritis without rheumatoid factor, left knee
M06.069	Rheumatoid arthritis without rheumatoid factor, unspecified knee
M06.071	Rheumatoid arthritis without rheumatoid factor, right ankle and foot
M06.072	Rheumatoid arthritis without rheumatoid factor, left ankle and foot
M06.079	Rheumatoid arthritis without rheumatoid factor, unspecified ankle and foot
M06.08	Rheumatoid arthritis without rheumatoid factor, vertebrae
M06.09	Rheumatoid arthritis without rheumatoid factor, multiple sites
M06.0A	Rheumatoid arthritis without rheumatoid factor, other specified site
M06.1	Adult-onset Still's disease
M06.80	Other specified rheumatoid arthritis, unspecified site
M06.811	Other specified rheumatoid arthritis, right shoulder
M06.812	Other specified rheumatoid arthritis, left shoulder
M06.819	Other specified rheumatoid arthritis, unspecified shoulder
M06.821	Other specified rheumatoid arthritis, right elbow
M06.822	Other specified rheumatoid arthritis, left elbow
M06.829	Other specified rheumatoid arthritis, unspecified elbow
M06.831	Other specified rheumatoid arthritis, right wrist
M06.832	Other specified rheumatoid arthritis, left wrist
M06.839	Other specified rheumatoid arthritis, unspecified wrist
M06.841	Other specified rheumatoid arthritis, right hand
M06.842	Other specified rheumatoid arthritis, left hand
M06.849	Other specified rheumatoid arthritis, unspecified hand
M06.851	Other specified rheumatoid arthritis, right hip
M06.852	Other specified rheumatoid arthritis, left hip
M06.859	Other specified rheumatoid arthritis, unspecified hip
M06.861	Other specified rheumatoid arthritis, right knee
M06.862	Other specified rheumatoid arthritis, left knee
M06.869	Other specified rheumatoid arthritis, unspecified knee
M06.871	Other specified rheumatoid arthritis, right ankle and foot
M06.872	Other specified rheumatoid arthritis, left ankle and foot
M06.879	Other specified rheumatoid arthritis, unspecified ankle and foot
M06.88	Other specified rheumatoid arthritis, vertebrae
M06.89	Other specified rheumatoid arthritis, multiple sites
M06.8A	Other specified rheumatoid arthritis, other specified site

Diagnosis Code	Description
M06.9	Rheumatoid arthritis, unspecified
M08.00	Unspecified juvenile rheumatoid arthritis of unspecified site
M08.0A	Unspecified juvenile rheumatoid arthritis, other specified site
M08.011	Unspecified juvenile rheumatoid arthritis, right shoulder
M08.012	Unspecified juvenile rheumatoid arthritis, left shoulder
M08.019	Unspecified juvenile rheumatoid arthritis, unspecified shoulder
M08.021	Unspecified juvenile rheumatoid arthritis, right elbow
M08.022	Unspecified juvenile rheumatoid arthritis, left elbow
M08.029	Unspecified juvenile rheumatoid arthritis, unspecified elbow
M08.031	Unspecified juvenile rheumatoid arthritis, right wrist
M08.032	Unspecified juvenile rheumatoid arthritis, left wrist
M08.039	Unspecified juvenile rheumatoid arthritis, unspecified wrist
M08.041	Unspecified juvenile rheumatoid arthritis, right hand
M08.042	Unspecified juvenile rheumatoid arthritis, left hand
M08.049	Unspecified juvenile rheumatoid arthritis, unspecified hand
M08.051	Unspecified juvenile rheumatoid arthritis, right hip
M08.052	Unspecified juvenile rheumatoid arthritis, left hip
M08.059	Unspecified juvenile rheumatoid arthritis, unspecified hip
M08.061	Unspecified juvenile rheumatoid arthritis, right knee
M08.062	Unspecified juvenile rheumatoid arthritis, left knee
M08.069	Unspecified juvenile rheumatoid arthritis, unspecified knee
M08.071	Unspecified juvenile rheumatoid arthritis, right ankle and foot
M08.072	Unspecified juvenile rheumatoid arthritis, left ankle and foot
M08.079	Unspecified juvenile rheumatoid arthritis, unspecified ankle and foot
M08.08	Unspecified juvenile rheumatoid arthritis, vertebrae
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites
M08.20	Juvenile rheumatoid arthritis with systemic onset, unspecified site
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder
M08.219	Juvenile rheumatoid arthritis with systemic onset, unspecified shoulder
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow
M08.229	Juvenile rheumatoid arthritis with systemic onset, unspecified elbow
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist
M08.239	Juvenile rheumatoid arthritis with systemic onset, unspecified wrist
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand
M08.249	Juvenile rheumatoid arthritis with systemic onset, unspecified hand
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip
M08.259	Juvenile rheumatoid arthritis with systemic onset, unspecified hip

Diagnosis Code	Description
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee
M08.269	Juvenile rheumatoid arthritis with systemic onset, unspecified knee
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot
M08.279	Juvenile rheumatoid arthritis with systemic onset, unspecified ankle and foot
M08.28	Juvenile rheumatoid arthritis with systemic onset, vertebrae
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites
M08.2A	Juvenile rheumatoid arthritis with systemic onset, other specified site
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.80	Other juvenile arthritis, unspecified site
M08.811	Other juvenile arthritis, right shoulder
M08.812	Other juvenile arthritis, left shoulder
M08.819	Other juvenile arthritis, unspecified shoulder
M08.821	Other juvenile arthritis, right elbow
M08.822	Other juvenile arthritis, left elbow
M08.829	Other juvenile arthritis, unspecified elbow
M08.831	Other juvenile arthritis, right wrist
M08.832	Other juvenile arthritis, left wrist
M08.839	Other juvenile arthritis, unspecified wrist
M08.841	Other juvenile arthritis, right hand
M08.842	Other juvenile arthritis, left hand
M08.849	Other juvenile arthritis, unspecified hand
M08.851	Other juvenile arthritis, right hip
M08.852	Other juvenile arthritis, left hip
M08.859	Other juvenile arthritis, unspecified hip
M08.861	Other juvenile arthritis, right knee
M08.862	Other juvenile arthritis, left knee
M08.869	Other juvenile arthritis, unspecified knee
M08.871	Other juvenile arthritis, right ankle and foot
M08.872	Other juvenile arthritis, left ankle and foot
M08.879	Other juvenile arthritis, unspecified ankle and foot
M08.88	Other juvenile arthritis, vertebrae
M08.89	Other juvenile arthritis, multiple sites
M08.90	Juvenile arthritis, unspecified, unspecified site
M08.9A	Juvenile arthritis, unspecified, other specified site
M08.911	Juvenile arthritis, unspecified, right shoulder
M08.912	Juvenile arthritis, unspecified, left shoulder
M08.919	Juvenile arthritis, unspecified, unspecified shoulder
M08.921	Juvenile arthritis, unspecified, right elbow
M08.922	Juvenile arthritis, unspecified, left elbow
M08.929	Juvenile arthritis, unspecified, unspecified elbow

Diagnosis Code	Description
M08.931	Juvenile arthritis, unspecified, right wrist
M08.932	Juvenile arthritis, unspecified, left wrist
M08.939	Juvenile arthritis, unspecified, unspecified wrist
M08.941	Juvenile arthritis, unspecified, right hand
M08.942	Juvenile arthritis, unspecified, left hand
M08.949	Juvenile arthritis, unspecified, unspecified hand
M08.951	Juvenile arthritis, unspecified, right hip
M08.952	Juvenile arthritis, unspecified, left hip
M08.959	Juvenile arthritis, unspecified, unspecified hip
M08.961	Juvenile arthritis, unspecified, right knee
M08.962	Juvenile arthritis, unspecified, left knee
M08.969	Juvenile arthritis, unspecified, unspecified knee
M08.971	Juvenile arthritis, unspecified, right ankle and foot
M08.972	Juvenile arthritis, unspecified, left ankle and foot
M08.979	Juvenile arthritis, unspecified, unspecified ankle and foot
M08.98	Juvenile arthritis, unspecified, vertebrae
M08.99	Juvenile arthritis, unspecified, multiple sites
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela

Background

Orencia is a fully human, soluble, fusion protein, selective co-stimulation modulator which inhibits T lymphocyte activation by binding to CD80 and CD86, thereby blocking interaction with CD28.[6,7] This interaction provides a costimulatory signal necessary for full activation of T lymphocytes.[5]

Benefit Considerations

Some Certificates of Coverage allow coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The enrollee-specific benefit document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy. Benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. See the Policy and Procedure addressing the treatment of serious rare diseases.

Clinical Evidence

Proven

Psoriatic Arthritis

A randomized, placebo controlled Phase 3 trial assessed the efficacy and safety of abatacept in adult patients (>18 years old) with psoriatic arthritis.[22] Patients were randomly assigned in a double-blind manner to receive either subcutaneous abatacept 125mg weekly or placebo for 24 weeks. Patients who had not achieved ≥ 20% improvement in swollen and tender joint counts from baseline to week 16 were switched to open-label abatacept weekly for 28 weeks. At the end of the open-label period, patients had the option of entering a 1 year, long-term extension. Primary efficacy endpoint was the proportion of patients with

ACR20 responses at week 24. Abatacept significantly increased ACR20 response versus placebo at week 24 (39.4% vs 22.3%; p<0.001). Although abatacept numerically increased Health Assessment Questionnaire–Disability Index response rates (reduction from baseline ≥0.35) at week 24, this was not statistically significant (31.0% vs 23.7%; p=0.097). The benefits of abatacept were seen in ACR20 responses regardless of TNF inhibitor exposure and in other musculoskeletal manifestations, but significance could not be attributed due to ranking below Health Assessment Questionnaire–Disability Index response in hierarchical testing. The benefit on psoriasis lesions was modest. Efficacy was maintained or improved up to week 52. Abatacept was well tolerated with no new safety signals. The authors concluded that abatacept treatment of PsA in achieved its primary end point, ACR20 response, showed beneficial trends overall in musculoskeletal manifestations and was well tolerated. There was only a modest impact on psoriasis lesions.

Rheumatoid Arthritis

In a Phase 3b double-blind, double-dummy, 6 month study, Genovese et al, compared the efficacy and safety of subcutanous (SC) and intravenous (IV) abatacept.[26] Patients with rheumatoid arthritis (RA) and with inadequate response to methotrexate (MTX), were randomzied to receive either 125mg SC abatacept on days 1 and 8 and weekly thereafter (plus an IV loading dose 10mg/kg on day 1) or IV abatacept 10mg/kg on days 1, 15, and 29 and every 4 weeks thereafter. The primary end point for determining the noninferiority of SC abatacept to IV abatacept was the proportion of patients in each group meeting the American College of Rheumatology 20% improvement criteria (achieving an ACR20 response) at month 6. Of 1,457 patients, 693 of 736 (94.2%) treated with SC abatacept and 676 of 721 (93.8%) treated with IV abatacept completed 6 months. At month 6, 76.0% (95% confidence interval 72.9, 79.2) of SC abatacept–treated patients versus 75.8% (95% confidence interval 72.6, 79.0) of IV abatacept–treated patients achieved an ACR20 response (estimated difference between groups 0.3% [95% confidence interval −4.2, 4.8]), confirming noninferiority of SC abatacept to IV abatacept. Onset and magnitude of ACR responses and disease activity and physical function improvements were comparable between the SC and IV abatacept–treated groups. The proportions of adverse events (AEs) and serious AEs over 6 months were 67.0% and 4.2%, respectively, in the SC abatacept–treated group and 65.2% and 4.9%, respectively, in the IV abatacept–treated group, with comparable frequencies of serious infections, malignancies, and autoimmune events between groups. SC injection site reactions (mostly mild) occurred in 19 SC abatacept (IV placebo)–treated patients (2.6%) and 18 IV abatacept (SC placebo)–treated patients (2.5%). Abatacept-induced antibodies occurred in 1.1% of SC abatacept–treated patients and 2.3% of IV abatacept–treated patients. No major differences in ACR responses were observed between intravenous and subcutaneous treatment groups in subgroups based on weight categories (less than 60 kg, 60 to 100 kg, and more than 100 kg). The authors concluded that SC abatacept provides efficacy and safety comparable with that of IV abatacept.

A randomized, multicenter, active controlled Phase 3b trial, the Assessing Very Early Rheumatoid arthritis Treatment (AVERT) trial (n=351) of 24 months, with a 12-month, double-blind treatment period, evaluated clinical remission with subcutaneous abatacept plus methotrexate (MTX) and abatacept monotherapy in patients with early rheumatoid arthritis (RA), and maintenance of remission following the rapid withdrawal of all RA treatment.[17] During the 12 month treatment period, patients were randomized (1:1:1) to receive abatacept plus MTX (n=119), abatacept monotherapy (n=116), or MTX monotherapy (n=116), stratified by corticosteroid use at baseline. Patients with a Disease Activity Score (DAS)28 (CRP) <3.2 at month 12 could enter the 12 month withdrawal period where abatacept was immediately stopped and MTX and steroids tapered over 1 month. Patients with DAS28 ≥ 3.2 discontinued the study. After month 15, patients in the withdrawal period who experienced a flare could re-start open label SC abatacept 125mg plus MTX. Co-primary endpoints were the proportion of randomized and treated patients in DAS-defined remission (CRP <2.6) at month 12 and months 12 and 18 for abatacept plus MTX versus MTX. For the abatacept plus MTX versus MTX, DAS28 (CRP) < 2.6 was achieved in 60.9% versus 45.2% (p=0.010) at 12 months, and following treatment withdrawal, in 14.8% versus 7.8% (p=0.045) at both 12 and 18 months. DAS28 (CRP) <2.6 was achieved for abatacept monotherapy in 42.5% (month 12) and 12.45% (both months 12 and 18). Both abatacept arms had a safety profile comparable to MTX alone. The authors concluded that abatacept plus MTX demonstrated efficacy compared with MTX alone in early RA, with a comparable safety profile to MTX. Abatacept achieved some sustained remission following withdrawal of all RA therapy in the respective groups.

Polyarticular Juvenile Idiopathic Arthritis

Brunner et al investigated the pharmacokinetics, effectiveness, and safety of subcutanous (SC) abatacept in patients with polyarticular juvenile idiopathic arthritis (PJIA) over 24 months.[27] This Phase 3, open-label, international, multicenter, single-arm study enrolled patients in two cohorts: cohort 1, agest 6 to 17 years and cohort 2, ages 2 to 5 years, each in whom treatment with ≥1 DMARD was unsuccessful. Patients received weight-tiered SC abatacept weekly: 10 to <25 kg (50 mg), 25 to <50 kg (87.5 mg), ≥50 kg (125 mg). Patients who had met the JIA–American College of Rheumatology 30% improvement criteria

(achieved a JIA-ACR 30 response) at month 4 were given the option to continue SC abatacept to month 24. The primary end point was the abatacept steady-state serum trough concentration (C_{minss}) in cohort 1 at month 4. Other outcome measures included JIA-ACR 30, 50, 70, 90, 100, and inactive disease status, the median Juvenile Arthritis Disease Activity Score in 71 joints using the C-reactive protein level (JADAS-71–CRP) over time, safety, and immunogenicity. The median abatacept C_{minss} at month 4 and at month 24 was above the target therapeutic exposure (10 µg/ml) in both cohorts. The percentage of patients who had achieved JIA-ACR 30, 50, 70, 90, or 100 responses or had inactive disease responses at month 4 (intent-to-treat population) was 83.2%, 72.8%, 52.6%, 28.3%, 14.5%, and 30.1%, respectively, in cohort 1 (n = 173) and 89.1%, 84.8%, 73.9%, 58.7%, 41.3%, and 50.0%, respectively, in cohort 2 (n = 46); the responses were maintained to month 24. Improvements were sustained to month 24, at which time 27 of 173 patients (cohort 1) and 11 of 22 patients (cohort 2) had achieved JADAS-71–CRP remission. No unexpected adverse events were reported; 4 of 172 patients (2.3%) in cohort 1 and 4 of 46 (8.7%) in cohort 2 developed anti-abatacept antibodies, with no clinical effects. The JIA ACR 30, 50, 70 responses assessed at 4 months in the 2 to 17-year-old patients were consistent with the results from the intravenous study, JIA-1.

The long-term extension (LTE) phase of a pivotal phase III study examining the efficacy and safety of abatacept in patients with juvenile idiopathic arthritis (JIA) reported the efficacy and safety outcomes of treatment (up to 10mg/kg every 4 weeks), with or without non-biologic DMARDs, for up to 7 years of follow-up.[19] One hundred fifty-three of 190 patients (80.5%) entered the LTE phase, with only 69 patients (36.3%) completing the study. The overall incidence rate (events per 100 patient-years) of adverse events decreased from 433.61 events during the short-term phase compared to 132.39 events during the LTE phase. Serious adverse events (6.82 vs. 5.60), malignancies (1.12 vs. 0), and autoimmune events (2.26 vs. 1.18) also were reduced. Serious infections were slightly increased (1.13 vs. 1.72). American College of Rheumatology (ACR) Pediatric 30 (Pedi 30), Pedi 70, responses, and clinically inactive disease status were maintained throughout the extension phase in those patients continuing to receive therapy. Improvements in the Child Health Questionnaire summary scores were also maintained over the course of the study. The authors concluded that long-term abatacept therapy, for up to 7 years, was associated with consistent safety, efficacy, and quality of life benefits in patients with JIA.

NCCN Recommended Uses

According to the NCCN Drugs & Biologics Compendium, NCCN recommends (2A) abatacept for the treatment of:

- Chronic graft-versus-host disease (GVHD) as additional therapy in conjunction with systemic corticosteroids following no response (steroid-refractory disease) to first-line therapy options
- Immune checkpoint inhibitor-related toxicities - Consider adding abatacept for the management of immunotherapy-related:
    - Severe (G3) or life-threatening (G4) myocarditis, pericarditis, arrhythmias, impaired ventricular function, or conduction abnormalities if no improvement within 24 hours of starting pulse-dose methylprednisolone

Unproven

Multiple Sclerosis

Khoury et al conducted ACCLAIM (A Cooperative Clinical Study of Abatacept in Multiple Sclerosis), a Phase II, randomized, double-blind, placebo-controlled, multi-center trial.[23] In the trial, 65 of 123 planned participants with relapsing-remitting multiple sclerosis (RRMS) were randomized to monthly intravenous infusions of abatacept or placebo for 24 weeks and then switched to the other treatment at 28 weeks. The primary endpoint was the mean number of new gadolinium-enhancing (Gd+) lesions obtained on magnetic resonance imaging (MRI) scans performed every 4 weeks. There was not a statistically significant difference observed between the abatacept and placebo groups for in mean number of new Gd+ MRI lesions. Additionally, no statistically significant differences were found in other MRI and clinical parameters of RRMS disease activity. The authors conclude that the ACCLAIM study did not demonstrate efficacy of abatacept in reducing the number of new Gd+ MRI lesions, or clinical measures of disease activity in RRMS.

A randomized, double-blind, placebo-controlled Phase II study of 128 patients was initiated to evaluate the use of abatacept in patients with relapsing-remitting multiple sclerosis.[8] The primary objective was to demonstrate the relative safety and preliminary clinical efficacy of 2 different doses of abatacept (10 mg/kg and 2 mg/kg) compared with placebo in subjects with relapsing-remitting MS by showing a reduction in the cumulative number of new or recurrent gadolinium-enhancing lesions on T1-weighted (Gd-T1) magnetic resonance imaging (MRI) over Day 85 through Day 225. However, the study terminated early because the Drug Safety Monitoring Board (DSMB) responsible for reviewing blinded safety data from the study expressed concerns that one of the treatment groups (subsequently found to be the 2 mg/kg abatacept group) had more subjects exhibiting an increase in Gd-enhancing T1-weighted MRI lesions and at least 1 multiple sclerosis exacerbation.

Systemic Lupus Erythematosus

A Phase II multi-center, randomized, double-blind, placebo-controlled study was conducted to evaluate the efficacy and safety of abatacept (n=121) versus placebo (n=59) for patients with systemic lupus erythematosus (SLE).[9] The abatacept group received the study drug (weight-tiered dosing) administered intravenously on Day 1, 15, 29, and every 28 days thereafter. Planned treatment duration for the double-blind period was 12 months. Prednisone or prednisone equivalent oral tablets was given on a defined tapering schedule at the time of randomization along with the study medication or placebo. The study failed to meet the primary efficacy endpoint, which was to assess the proportion of subjects who experienced a new SLE flare, based on adjudication of all BILAG 'A' or 'B' events, following resolution of the entry flare and/or the start of prednisone or prednisone equivalent taper schedule across the 12-month double-blind treatment period.

Uveitis Associated with Behçet's Disease

Blockade of antigen non-specific co-stimulatory signals is theorized to be effective for Behçet's disease.[13,14] However, there is currently insufficient clinical evidence of the safety and efficacy of abatacept in published peer-reviewed medical literature for this condition.

Professional Societies

Psoriatic Arthritis

In 2018, the American College of Rheumatology and the National Psoriasis Foundation published treatment guideline for the treatment of psoriatic arthritis. In regards to psoriatic arthritis (PsA) and abatacept, the guidelines state:

- Recommendations for treatment of patients with active psoriatic arthritis despite treatment with an oral small molecule (OSM):
  - Switch to a TNFi biologic over abatacept:
    - Conditional recommendation based on low-quality evidence; may consider abatacept if the patient has contraindications to TNFi biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease.
  - Switch to an IL-17i biologic over abatacept
    - Conditional recommendation based on low-quality evidence; may consider abatacept in patients with recurrent or serious infections.
  - Switch to an IL-12/23i biologic over abatacept
    - Conditional recommendation based on low-quality evidence; may consider abatacept in patients with recurrent or serious infections.
- Recommendations for treatment of patients with active psoriatic arthritis despite treatment with a TNFi biologic, as monotherapy or in combination with MTX
  - Switch to a different TNFi biologic over switching to abatacept
    - Conditional recommendation based on low-quality evidence; may consider abatacept if the patient had a primary TNFi biologic efficacy failure or TNFi biologic–associated serious adverse effect.
  - Switch to an IL-17i biologic over abatacept
    - Conditional recommendation based on low-quality evidence; may consider abatacept if the patient prefers IV dosing or in patients with recurrent or serious infections.
  - Switch to an IL-12/23i biologic over abatacept
    - Conditional recommendation based on of low-quality evidence; may consider abatacept if the patient prefers IV dosing or in patients with recurrent or serious infections

The American Academy of Dermatology (AAD) defines psoriatic arthritis (PsA) as mild, moderate, or severe. Where mild disease responds to NSAIDs, moderate disease requires DMARDs or TNF blockers. Appropriate treatment of severe PsA requires DMARDs plus TNF blockers or other biologic therapies. If PsA is diagnosed, treatment should be initiated to alleviate signs and symptoms of PsA, inhibit structural damage, and maximize quality of life (QOL). According to the 2019 AAD Practice Guidelines for the management of psoriatic arthritis, the potential importance of TNF-α in the pathophysiology of PsA is underscored by the observation that there are elevated levels of TNF-α in the synovium, joint fluid, and skin of patients with PsA. The guidelines support the use of infliximab for PsA based on evidence ranked as consistent, good quality, and patient-oriented. (Strength of Recommendation: A).

Rheumatoid Arthritis

The 2015 American College of Rheumatology (ACR) RA treatment guideline addresses the use of DMARDS, biologics, tofacitinib, and glucocorticoids in early (<6 months) and established (≥ 6 months) RA and the use of various treatment approaches in frequently encountered clinical scenarios, including treat-to-target, switching between therapies, tapering of therapy, the use of biologics and DMARDs in high-risk RA patients, vaccination in patients with RA receiving DMARDs or biologics, TB screening with biologics or tofacitinib, and laboratory monitoring with DMARDs.[21] The guideline recommendations apply to common clinical situations, since the panel considered issues common to most patients, not exceptions. Recommendations are classified as either strong or conditional. A strong recommendation means that the panel was confident that the desirable effects of following the recommendation outweigh the undesirable effects (or vice versa), so the course of action would apply to most patients, and only a small proportion would not want to follow the recommendation. A conditional recommendation means that the desirable effects of following the recommendation probably outweigh the undesirable effects, so the course of action would apply to the majority of patients, but some may not want to follow the recommendation. As a result, conditional recommendations are preference sensitive and warrant a shared decision-making approach.

Supplementary Appendix 5, of the 2015 ACR RA guideline, summarizes recommendations for patients with early RA, established RA, and high-risk comorbidities:[21]

Recommendations for Early RA Patients

- The panel strongly recommends using a treat-to-target strategy rather than a non-targeted approach, regardless of disease activity level. The ideal target should be low disease activity or remission, as determined by the clinician and the patient. In some cases, another target may be chosen because risk tolerance by patients or comorbidities may mitigate the usual choices.
- For DMARD-naïve patients with early, symptomatic RA, the panel strongly recommends DMARD monotherapy over double or triple DMARD therapy in patients with low disease activity and conditionally recommends DMARD monotherapy over double or triple DMARD therapy in patients with moderate or high disease activity. Methotrexate should be the preferred initial therapy for most patients with early RA with active disease.
- For patients with moderate or high disease activity despite DMARD therapy (with or without glucocorticoids), the panel strongly recommends treatment with a combination of DMARDs *or* a TNFi *or* a non-TNF biologic, with or without methotrexate (MTX) in no particular order of preference, rather than continuing DMARD monotherapy alone. Biologic therapy should be used in combination with MTX over biologic monotherapy, when possible, due to superior efficacy.
- For patients with moderate or high disease activity despite any of the above DMARD or biologic therapies, the panel conditionally recommends adding low-dose glucocorticoids (defined as ≤10 mg/day of prednisone or equivalent). Low-dose glucocorticoids may also be used in patients who need a bridge until realizing the benefits of DMARD therapy. The risk/benefit ratio of glucocorticoid therapy is favorable as long as the dose is low and the duration of therapy is short.
- For patients experiencing a flare of RA, the panel conditionally recommends adding short-term glucocorticoids (< 3 months of treatment) at the lowest possible dose for the shortest possible duration, to provide a favorable benefit-risk ratio for the patient.

Recommendations for Established RA Patients

- The panel strongly recommends using a treat-to-target strategy rather than a non-targeted approach, regardless of disease activity level. The ideal target should be low disease activity or remission, as determined by the clinician and the patient. In some cases, however, another target may be chosen because tolerance by patients or comorbidities may mitigate the usual choices.
- For DMARD-naïve patients with low disease activity, the panel strongly recommends using DMARD monotherapy over a TNFi. For DMARD-naïve patients with moderate or high disease activity, the panel conditionally recommends DMARD monotherapy over double or triple DMARD therapy and DMARD monotherapy over tofacitinib. In general, MTX should be the preferred initial therapy for most patients with established RA with active disease.
- For patients with moderate or high disease activity despite DMARD monotherapy including methotrexate, the panel strongly recommends using combination DMARDs or adding a TNFi or a non-TNF biologic or tofacitinib (all choices with or without methotrexate) in no particular order of preference, rather than continuing DMARD monotherapy alone. Biologic therapy should be used in combination with MTX over biologic monotherapy, when possible, due to its superior efficacy.

For All Scenarios for Established RA Below, Treatment May Be With or Without MTX

- For moderate or high disease activity despite TNFi therapy in patients currently not on a DMARD, the panel strongly recommends that one or two DMARDs be added to TNFi therapy rather than continuing TNFi therapy alone.
- If disease activity is moderate or high despite single TNFi biologic therapy, the panel conditionally recommends using a non-TNF biologic.
- If disease activity is moderate or high despite non-TNF biologic therapy, the panel conditionally recommends using another non-TNF biologic. However, if a patient has failed multiple non-TNF biologics and they are TNFi-naïve with moderate or high disease activity, the panel conditionally recommends treatment with a TNFi.
- For patients with moderate or high disease activity despite prior treatment with at least one TNFi and at least one non-TNF-biologic (sequentially, not combined), the panel conditionally recommends first treating with another non-TNF biologic. However, when a non-TNF biologic is not an option (e.g., patient declines non-TNF biologic therapy due to inefficacy or side effects), the panel conditionally recommends treatment with tofacitinib.
- If disease activity is moderate or high despite the use of multiple (2+) TNFi therapies (in sequence, not concurrently), the panel conditionally recommends non-TNF biologic therapy and then conditionally treating with tofacitinib when a non-TNF biologic is not an option.
- If disease activity is moderate or high despite any of the above DMARD or biologic therapies, the panel conditionally recommends adding low-dose glucocorticoids.
- If patients with established RA experience an RA flare while on DMARD, TNFi, or non-TNF biologic therapy, the panel conditionally recommends adding short-term glucocorticoids (< 3 months of treatment) at the lowest possible dose and for shortest possible duration to provide the best benefit-risk ratio for the patient.
- In patients with established RA and low disease activity but not remission, the panel strongly recommends continuing DMARD therapy, TNFi, non-TNF biologic or tofacitinib rather than discontinuing respective medication.
- In patients with established RA currently in remission, the panel conditionally recommends tapering DMARD therapy, TNFi, non-TNF biologic, or tofacitinib.
- The panel strongly recommends not discontinuing all therapies in patients with established RA in disease remission.

Recommendations for RA Patients with High-Risk Comorbidities

Congestive Heart Failure

- In patients with established RA with moderate or high disease activity and New York Heart Association (NYHA) class III or IV congestive heart failure (CHF), the panel conditionally recommends using combination DMARD therapy, a non-TNF biologic, or tofacitinib rather than a TNFi.
- If patients in this population are treated with a TNFi and their CHF worsens while on the TNFi, the panel conditionally recommends switching to combination DMARD therapy, a non-TNF biologic, or tofacitinib rather than a different TNFi.

Hepatitis B

- In patients with established RA with moderate or high disease activity and evidence of active hepatitis B infection (hepatitis surface antigen positive > 6 months), who are receiving or have received effective antiviral treatment, the panel strongly recommends treating them the same as patients without this condition.
- For a patient with natural immunity from prior exposure to hepatitis B (i.e., HB core antibody and HBS antibody positive and normal liver function tests), the panel recommends the same therapies as those without such findings as long as the patient's viral load is monitored.
- For patients with chronic hepatitis B who are untreated, referral for antiviral therapy is appropriate prior to immunosuppressive therapy.

Hepatitis C

- In patients with established RA with moderate or high disease activity and evidence of chronic hepatitis C virus (HCV) infection, who are receiving or have received effective antiviral treatment, the panel conditionally recommends treating them the same as the patients without this condition.
- The panel recommends that rheumatologists work with gastroenterologists and/or hepatologists who would monitor patients and reassess the appropriateness of antiviral therapy. This is important considering the recent availability of highly effective therapy for HCV, which may lead to a greater number of HCV patients being treated successfully.
- If the same patient is not requiring or receiving antiviral treatment for their hepatitis C, the panel conditionally recommends using DMARD therapy rather than TNFi.

Malignancy

- Previous Melanoma and Non-Melanoma Skin Cancer
  - In patients with established RA and moderate or high disease activity and a history of previously treated or untreated skin cancer (melanoma or non-melanoma), the panel conditionally recommends the use of DMARD therapy over biologics or tofacitinib.
- Previous Lymphoproliferative Disorders
  - In patients with established RA with moderate or high disease activity and a history of a previously treated lymphoproliferative disorder, the panel strongly recommends using rituximab rather than a TNFi and conditionally recommends using combination DMARD therapy, abatacept or tocilizumab rather than TNFi.
- Previous Solid Organ Cancer
  - In patients with established RA with moderate or high disease activity and previously treated solid organ cancer, the panel conditionally recommends that they be treated for RA just as one would treat an RA patient without a history of solid organ cancer.
- Serious Infections
  - In patients with established RA with moderate or high disease activity and previous serious infection(s), the panel conditionally recommends using combination DMARD therapy or abatacept rather than TNFi.

Juvenile Idiopathic Arthritis

The 2019 American College of Rheumatology (ACR) and Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis include abatacept.[2]

- General medication recommendations for children and adolescents with JIA and polyarthritis:
  - Biologic DMARDS:
    - In children and adolescents with JIA and polyarthritis initiating treatment with a biologic (etanercept, adalimumab, golimumab, abatacept, or tocilizumab) combination therapy with a DMARD is conditionally recommended over biologic monotherapy
- General guidelines for the initial and subsequent treatment of children and adolescents with JIA and polyarthritis
  - Subsequent therapy: Moderate/high disease activity (cJADAS-10 >2.5)
    - If patient is receiving DMARD monotherapy: Adding a biologic to original DMARD is conditionally recommended over changing to a second DMARD. Adding a biologic is conditionally recommended over changing to triple DMARD therapy.
    - If patient is receiving first TNFi (± DMARD): Switching to a non-TNFi biologic (tocilizumab or abatacept) is conditionally recommended over switching to a second TNFi. A second TNFi may be appropriate for patients with good initial response to their first TNFi (i.e., secondary failure).
    - If patient is receiving second biologic: Using TNFi, abatacept, or tocilizumab (depending on prior biologics received) is conditionally recommended over rituximab.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Orencia is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Orencia may be used as monotherapy or concomitantly with DMARDs other than tumor necrosis factor (TNF) antagonists.[5]

Orencia is also indicated for reducing signs and symptoms in pediatric patients 6 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis. Orencia may be used as monotherapy or concomitantly with methotrexate. Orencia is also indicated for the treatment of adult patients with active psoriatic arthritis.[5]

The labeling for Orencia states that it should not be administered concomitantly with TNF antagonists or with other biologic RA therapy, such as Kineret (anakinra), an interleukin-1 receptor antagonist. In controlled clinical trials in patients with adult RA, patients receiving concomitant Orencia and TNF antagonist therapy experienced more infections (63%) and serious infections (4.4%) compared to patients treated with only TNF antagonists (43% and 0.8%, respectively). These trials failed to demonstrate

superiority of results with concomitant administration of Orencia and TNF antagonists. Therefore, clinical evidence does not support concurrent therapy with Orencia and TNF antagonists.[5]

Orencia prefilled syringes and Orencia ClickJect autoinjectors are intended for use under the guidance of a physician or healthcare practitioner. After proper training in subcutaneous injection technique, a patient or caregiver may self-inject Orencia if a physician/healthcare practitioner determines that it is appropriate. Patients and caregivers should be instructed to follow the directions provided in the Instructions for Use section of the prescribing information for additional details on medication administration.[5]

Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for Orencia® (abatacept). Local Coverage Determinations (LCDs)/Local Coverage Articles (LCDs) exist; refer to the LCDs/LCAs for Drug and Biological Infusions.

In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals. (Accessed January 31, 2020)

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Policy History/Revision Information

Date	Summary of Changes
10/01/2020	Applicable Codes • Updated list of applicable ICD-10 diagnosis codes to reflect annual edits; added M05.7A, M05.8A, M06.0A, M06.8A, M08.0A, M08.2A, and M08.9A

Date	Summary of Changes
	Supporting Information • Archived previous policy version 2020D0039M

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.