

**Texas Prior Authorization Program
Clinical Criteria**

Drug/Drug Class**Lupus Agents**

This criteria was recommended for review by the MCOs to ensure appropriate and safe utilization

Clinical Criteria Information Included in this Document**Benlysta (belimumab)**

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Lupkynis (voclosporin)

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Revision Notes

Initial publication and presentation to the DUR Board



Benlysta (belimumab)

Drugs Requiring Prior Authorization

Label Name	GCN
BENLYSTA 200 MG/ML AUTOINJECT	43658
BENLYSTA 200 MG/ML SYRINGE	43661



Benlysta (belimumab)

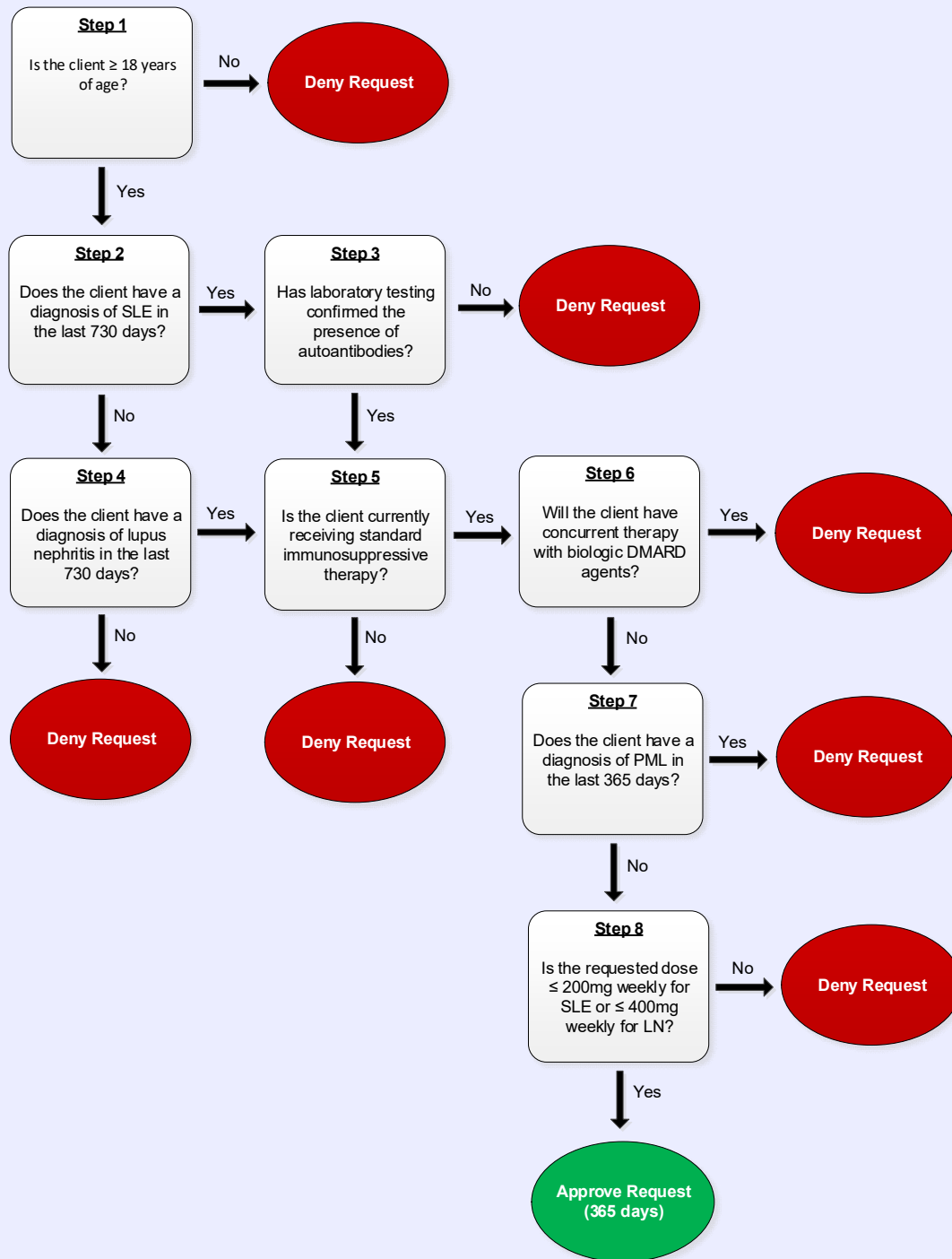
Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 18 years of age?
 Yes (Go to #2)
 No (Deny)
2. Does the client have a diagnosis of **systemic lupus erythematosus (SLE)** in the last 730 days?
 Yes (Go to #3)
 No (Go to #4)
3. Has laboratory testing confirmed the presence of autoantibodies? [Manual]
 Yes (Go to #5)
 No (Deny)
4. Does the client have a diagnosis of **lupus nephritis (LN)** in the last 730 days?
 Yes (Go to #5)
 No (Deny)
5. Is the client currently receiving **standard immunosuppressive therapy**?
 Yes (Go to #6)
 No (Deny)
6. Will the client have concurrent therapy with **biologic DMARD agents**?
 Yes (Deny)
 No (Go to #7)
7. Does the client have a diagnosis of **progressive multifocal leukoencephalopathy (PML)** in the last 365 days?
 Yes (Deny)
 No (Go to #8)
8. Is the requested dose less than or equal to (\leq) 200mg weekly for SLE or less than or equal to (\leq) 400mg weekly for LN?
 Yes (Approve – 365 days)
 No (Deny)



Benlysta (belimumab)

Clinical Criteria Logic Diagram





Lupkynis (voclosporin)

Drugs Requiring Prior Authorization

Label Name	GCN
LUPKYNIS 7.9 MG CAPSULE	49037



Lupkynis (voclosporin)

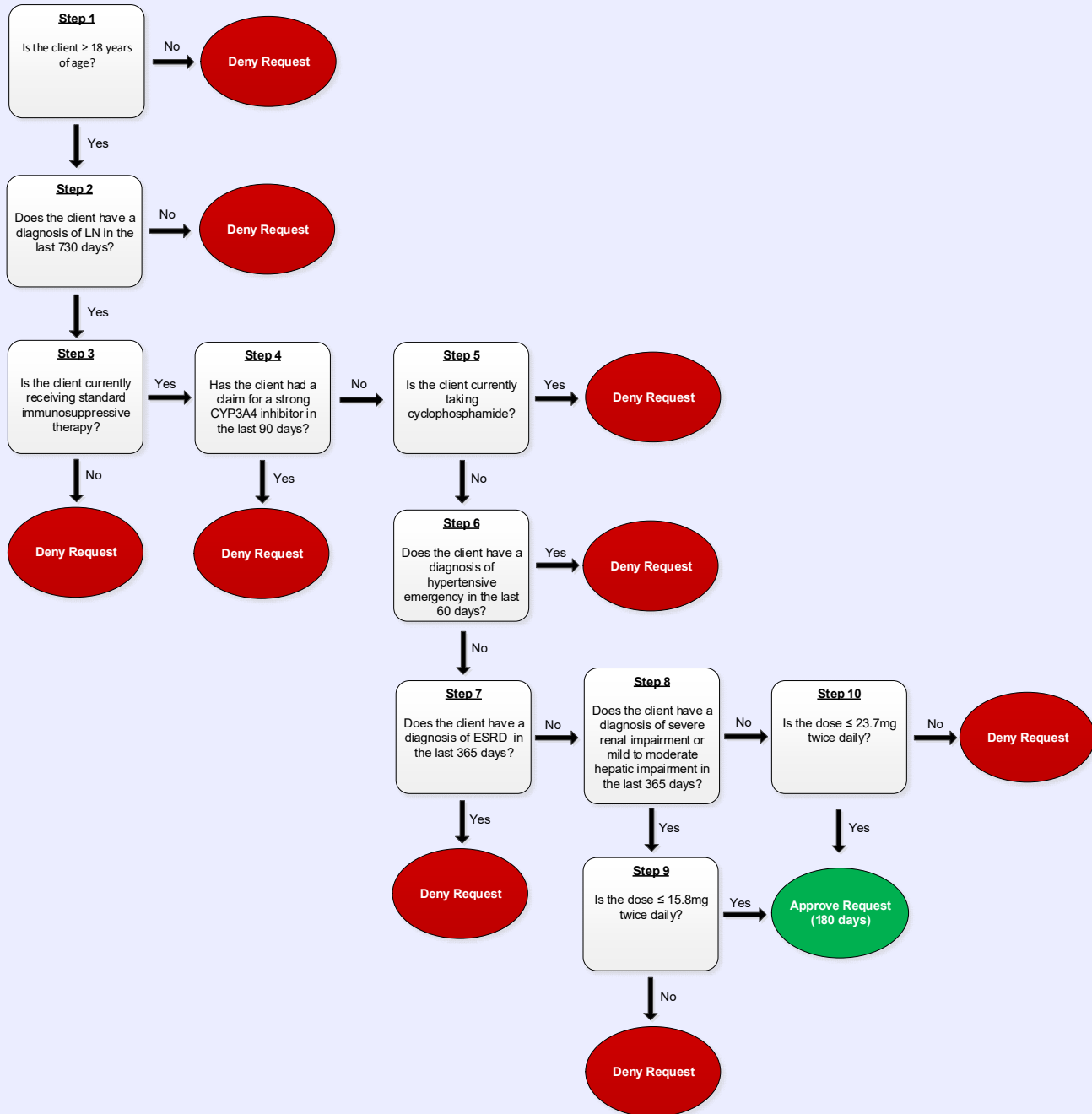
Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 18 years of age?
 Yes (Go to #2)
 No (Deny)
2. Does the client have a diagnosis of **lupus nephritis (LN)** in the last 730 days?
 Yes (Go to #3)
 No (Deny)
3. Is the client currently receiving **standard immunosuppressive therapy**?
 Yes (Go to #4)
 No (Deny)
4. Has the client had a claim for a **strong CYP3A4 inhibitor** in the last 90 days?
 Yes (Deny)
 No (Go to #5)
5. Is the client currently taking **cyclophosphamide**?
 Yes (Deny)
 No (Go to #6)
6. Does the client have a diagnosis of **hypertensive emergency** in the last 60 days?
 Yes (Deny)
 No (Go to #7)
7. Does the client have a diagnosis of **end stage renal disease (ESRD)** in the last 365 days?
 Yes (Deny)
 No (Go to #8)
8. Does the client have a diagnosis of **severe renal impairment or mild to moderate hepatic impairment** in the last 365 days?
 Yes (Go to #9)
 No (Go to #10)
9. Is the dose less than or equal to (\leq) 15.8mg twice daily?
 Yes (Approve – 180 days)
 No (Deny)
10. Is the dose less than or equal to (\leq) 23.7mg twice daily?
 Yes (Approve – 180 days)
 No (Deny)



Lupkynis (voclosporin)

Clinical Criteria Logic Diagram





Lupus Agents

Clinical Criteria Supporting Tables

Systemic Lupus Erythematosus	
ICD-10 Code	Description
M320	DRUG-INDUCED SYSTEMIC LUPUS ERYTHEMATOSUS
M3210	SYSTEMIC LUPUS ERYTHEMATOSUS, ORGAN OR SYSTEM INVOLVEMENT UNSPECIFIED
M3211	ENDOCARDITIS IN SYSTEMIC LUPUS ERYTHEMATOSUS
M3212	PERICARDITIS IN SYSTEMIC LUPUS ERYTHEMATOSUS
M3213	LUNG INVOLVEMENT IN SYSTEMIC LUPUS ERYTHEMATOSUS
M3215	TUBULO-INTERSTITIAL NEPHROPATHY IN SYSTEMIC LUPUS ERYTHEMATOSUS
M3219	OTHER ORGAN OR SYSTEM INVOLVEMENT IN SYSTEMIC LUPUS ERYTHEMATOSUS
M328	OTHER FORMS OF SYSTEMIC LUPUS ERYTHEMATOSUS
M329	SYSTEMIC LUPUS ERYTHEMATOSUS, UNSPECIFIED

Lupus Nephritis	
ICD-10 Code	Description
M3214	GLOMERULAR DISEASE IN SYSTEMIC LUPUS ERYTHEMATOSUS

Standard Immunosuppressive Therapy	
GCN	Label Name
46771	AZATHIOPRINE 50 MG TABLET
47563	CELLCEPT 200 MG/ML ORAL SUSP
47560	CELLCEPT 250 MG CAPSULE
47561	CELLCEPT 500 MG TABLET
42890	CHLOROQUINE PH 250 MG TABLET
42891	CHLOROQUINE PH 500 MG TABLET
42940	HYDROXYCHLOROQUINE 200 MG TABLET
46771	IMURAN 50 MG TABLET
38489	METHOTREXATE 2.5 MG TABLET
38466	METHOTREXATE 50 MG/ 2 ML VIAL
18936	METHOTREXATE 50 MG/2 ML VIAL
47560	MYCOPHENOLATE 250 MG CAPSULE

Standard Immunosuppressive Therapy	
GCN	Label Name
47561	MYCOPHENOLATE 500 MG TABLET
19646	MYCOPHENOLIC ACID DR 180 MG TAB
19647	MYCOPHENOLIC ACID DR 360 MG TAB
19646	MYFORTIC 180 MG TABLET
19647	MYFORTIC 360 MG TABLET
35427	OTREXUP 10 MG/0.4 ML AUTO-INJ
35428	OTREXUP 15 MG/0.4 ML AUTO-INJ
35437	OTREXUP 20 MG/0.4 ML AUTO-INJ
35438	OTREXUP 25 MG/0.4 ML AUTO-INJ
42940	PLAQUENIL 200 MG TABLET
27171	PREDNISONE 1 MG TABLET
27172	PREDNISONE 10 MG TABLET
27173	PREDNISONE 2.5 MG TABLET
27174	PREDNISONE 20 MG TABLET
27176	PREDNISONE 5 MG TABLET
27160	PREDNISONE 5 MG/5 ML SOLUTION
27161	PREDNISONE 5 MG/5 ML SOLUTION
27177	PREDNISONE 50 MG TABLET
06484	TREXALL 10MG TABLET
13135	TREXALL 15MG TABLET
13134	TREXALL 5MG TABLET
38485	TREXALL 7.5MG TABLET
43319	XATMEP 2.5MG/ML ORAL SOLUTION

Biologic DMARDs	
GCN	Description
35486	ACTEMRA 162MG/0.9ML SYRINGE
23471	CIMZIA 200MG/ML STARTER KIT
23471	CIMZIA 200MG/ML SYRINGE KIT
37789	COSENTYX 150MG/ML PEN INJECT
37788	COSENTYX 150MG/ML SYRINGE
52651	ENBREL 25MG KIT
98398	ENBREL 25MG/0.5ML SYRINGE
43294	ENBREL 50 MG/ML MINI CARTRIDGE
97724	ENBREL 50MG/ML SURECLICK SYRINGE
23574	ENBREL 50MG/ML SYRINGE
44659	HUMIRA (CF) 10 MG/0.1 ML SYRINGE

Biologic DMARDs	
GCN	Description
44664	HUMIRA (CF) 20 MG/0.2 ML SYRINGE
43505	HUMIRA (CF) 40 MG/0.4 ML SYRINGE
43904	HUMIRA (CF) PEDI CROHN 80 MG/0.8
44677	HUMIRA (CF) PEDI CROHN 80-40MG
44014	HUMIRA (CF) PEN CRHN-UC-HS 80 MG
44954	HUMIRA (CF) PEN PS-UV-AHS 80-40 MG
37262	HUMIRA 10 MG/0.2 ML SYRINGE
99439	HUMIRA 20 MG/0.4 ML SYRINGE
18924	HUMIRA 40 MG/0.8 ML SYRINGE
18924	HUMIRA PEDI CROHN 40 MG/0.8 ML
43506	HUMIRA PEN 40 MG/0.4 ML
97005	HUMIRA PEN 40 MG/0.8 ML
97005	HUMIRA PEN CROHN-UC-HS 40 MG
97005	HUMIRA PEN PS-UV-ADOL HS 40 MG
43148	ILARIS 150MG/ML VIAL
27445	ILARIS 180MG VIAL
44269	KEVZARA 150 MG/1.14 ML PEN INJ
43223	KEVZARA 150 MG/1.14 ML SYRINGE
44277	KEVZARA 200 MG/1.14 ML PEN INJ
43224	KEVZARA 200 MG/1.14 ML SYRINGE
14867	KINERET 100MG/0.67ML SYRINGE
30289	ORENCIA 125MG/ML SYRINGE
43389	ORENCIA 50MG/0.4ML SYRINGE
43397	ORENCIA 87.5MG/0.7ML SYRINGE
41656	ORENCIA CLICKJECT 125MG/ML
37765	OTEZLA 28 DAY STARTER PACK
36172	OTEZLA 30 MG TABLET
43055	SILIQ 210 MG/1.5 ML SYRINGE
35001	SIMPONI 100MG/ML PEN INJECTOR
34697	SIMPONI 100MG/ML SYRINGE
22533	SIMPONI 50MG/0.5ML PEN INJECTOR
22536	SIMPONI 50MG/0.5ML SYRINGE
34983	SIMPONI ARIA 50MG/4ML VIAL
28158	STELARA 45 MG/0.5 ML SYRINGE
40848	TALTZ 80 MG/ML AUTOINJ
40848	TALTZ 80 MG/ML SYRINGE
43612	TREMFYA 100 MG/ML SYRINGE

Progressive Multifocal Leukoencephalopathy [PML]	
ICD-10 Code	Description
A812	PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY

Strong CYP3A4 Inhibitors	
GCN	Description
19952	ATAZANAVIR SULFATE 150MG CAP
19953	ATAZANAVIR SULFATE 200MG CAP
97430	ATAZANAVIR SULFATE 300MG CAP
11670	CLARITHROMYCIN 125 MG/5 ML SUS
48852	CLARITHROMYCIN 250 MG TABLET
11671	CLARITHROMYCIN 250 MG/5 ML SUS
48851	CLARITHROMYCIN 500 MG TABLET
48850	CLARITHROMYCIN ER 500 MG TAB
26820	CRIXIVAN 200 MG CAPSULE
26822	CRIXIVAN 400 MG CAPSULE
37797	EVOTAZ 300-150MG TABLET
40092	GENVOYA TABLET
23952	INVIRASE 500 MG TABLET
49100	ITRACONAZOLE 10 MG/ML SOLUTION
49101	ITRACONAZOLE 100 MG CAPSULE
99101	KALETRA 100-25 MG TABLET
25919	KALETRA 200-50 MG TABLET
31782	KALETRA 400-100/5 ML ORAL SOLU
42590	KETOCONAZOLE 200 MG TABLET
31485	KORLYM 300 MG TABLET
64269	LANSOPRAZOL-AMOXICIL-CLARITHRO
16406	NEFAZODONE 100MG TABLET
16407	NEFAZODONE 150MG TABLET
16408	NEFAZODONE 200MG TABLET
16409	NEFAZODONE 250MG TABLET
16404	NEFAZODONE 50MG TABLET
40309	NORVIR 100 MG POWDER PACKET
28224	NORVIR 100 MG TABLET
26810	NORVIR 80 MG/ML SOLUTION
26502	NOXAFIL 40 MG/ML SUSPENSION
35649	NOXAFIL DR 100 MG TABLET
32137	OMECLAMOX-PAK COMBO PACK
37367	PREZCOBIX 800-150MG TABLET
31201	PREZISTA 100MG/ML SUSPENSION

Strong CYP3A4 Inhibitors	
GCN	Description
23489	PREZISTA 150MG TABLET
99434	PREZISTA 600MG TABLET
16759	PREZISTA 75MG TABLET
33723	PREZISTA 800MG TABLET
19952	REYATAZ 150MG CAPSULE
19953	REYATAZ 200MG CAPSULE
37430	REYATAZ 300MG CAPSULE
36647	REYATAZ 50MG POWDER PACK
28224	RITONAVIR 100 MG TABLET
49100	SPORANOX 10 MG/ML SOLUTION
49101	SPORANOX 100 MG CAPSULE
33130	STRIBILD TABLET
43968	SYM TUZA 800-150-200-10 MG TAB
45848	TOLSURA 65 MG CAPSULE
36468	TYBOST 150MG TABLET
17498	VFEND 200 MG TABLET
21513	VFEND 40 MG/ML SUSPENSION
17497	VFEND 50 MG TABLET
17499	VFEND IV 200 MG VIAL
37614	VIEKIRA PAK
40312	VIRACEPT 250 MG TABLET
19717	VIRACEPT 625 MG TABLET
17498	VORICONAZOLE 200 MG TABLET
17499	VORICONAZOLE 200 MG VIAL
21513	VORICONAZOLE 40 MG/ML SUSP
17497	VORICONAZOLE 50 MG TABLET
36884	ZYDELIG 100MG TABLET
36885	ZYDELIG 150MG TABLET

Cyclophosphamide	
GCN	Label Name
35317	CYCLOPHOSPHAMIDE 25 MG CAPSULE
35318	CYCLOPHOSPHAMIDE 50 MG CAPSULE

Hypertensive Emergency	
ICD-10 Code	Description
I160	HYPERTENSIVE URGENCY

Hypertensive Emergency	
ICD-10 Code	Description
I161	HYPERTENSIVE EMERGENCY
I169	HYPERTENSIVE CRISIS, UNSPECIFIED

ESRD	
ICD-10 Code	Description
N186	END STAGE RENAL DISEASE

Severe Renal Impairment or Mild to Moderate Hepatic Impairment	
ICD-10 Code	Description
B160	ACUTE HEPATITIS B WITH DELTA-AGENT WITH HEPATIC COMA
B161	ACUTE HEPATITIS B WITH DELTA-AGENT WITHOUT HEPATIC COMA
B162	ACUTE HEPATITIS B WITHOUT DELTA-AGENT WITH HEPATIC COMA
B169	ACUTE HEPATITIS B WITHOUT DELTA-AGENT AND WITHOUT HEPATIC COMA
B170	ACUTE DELTA-(SUPER) INFECTION OF HEPATITIS B CARRIER
B1710	ACUTE HEPATITIS C WITHOUT HEPATIC COMA
B1711	ACUTE HEPATITIS C WITH HEPATIC COMA
B172	ACUTE HEPATITIS E
B178	OTHER SPECIFIED ACUTE VIRAL HEPATITIS
B179	ACUTE VIRAL HEPATITIS, UNSPECIFIED
B180	CHRONIC VIRAL HEPATITIS B WITH DELTA-AGENT
B181	CHRONIC VIRAL HEPATITIS B WITHOUT DELTA-AGENT
B182	CHRONIC VIRAL HEPATITIS C
B188	OTHER CHRONIC VIRAL HEPATITIS
B189	CHRONIC VIRAL HEPATITIS, UNSPECIFIED
B190	UNSPECIFIED VIRAL HEPATITIS WITH HEPATIC COMA
B1910	UNSPECIFIED VIRAL HEPATITIS B WITHOUT HEPATIC COMA
B1911	UNSPECIFIED VIRAL HEPATITIS B WITH HEPATIC COMA
B1920	UNSPECIFIED VIRAL HEPATITIS C WITHOUT HEPATIC COMA
B1921	UNSPECIFIED VIRAL HEPATITIS C WITH HEPATIC COMA
B199	UNSPECIFIED VIRAL HEPATITIS WITHOUT HEPATIC COMA
K700	ALCOHOLIC FATTY LIVER
K7010	ALCOHOLIC HEPATITIS WITHOUT ASCITES
K7011	ALCOHOLIC HEPATITIS WITH ASCITES
K702	ALCOHOLIC FIBROSIS AND SCLEROSIS OF LIVER
K7030	ALCOHOLIC CIRRHOSIS OF LIVER WITHOUT ASCITES
K7031	ALCOHOLIC CIRRHOSIS OF LIVER WITH ASCITES

Severe Renal Impairment or Mild to Moderate Hepatic Impairment	
ICD-10 Code	Description
K7040	ALCOHOLIC HEPATIC FAILURE WITHOUT COMA
K7041	ALCOHOLIC HEPATIC FAILURE WITH COMA
K709	ALCOHOLIC LIVER DISEASE, UNSPECIFIED
K710	TOXIC LIVER DISEASE WITH CHOLESTASIS
K7110	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITHOUT COMA
K7111	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITH COMA
K712	TOXIC LIVER DISEASE WITH ACUTE HEPATITIS
K713	TOXIC LIVER DISEASE WITH CHRONIC PERSISTENT HEPATITIS
K714	TOXIC LIVER DISEASE WITH CHRONIC LOBULAR HEPATITIS
K7150	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITHOUT ASCITES
K7151	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITH ASCITES
K716	TOXIC LIVER DISEASE WITH HEPATITIS, NOT ELSEWHERE CLASSIFIED
K717	TOXIC LIVER DISEASE WITH FIBROSIS AND CIRRHOSIS OF LIVER
K718	TOXIC LIVER DISEASE WITH OTHER DISORDERS OF LIVER
K719	TOXIC LIVER DISEASE, UNSPECIFIED
K7200	ACUTE AND SUBACUTE HEPATIC FAILURE WITHOUT COMA
K7201	ACUTE AND SUBACUTE HEPATIC FAILURE WITH COMA
K7210	CHRONIC HEPATIC FAILURE WITHOUT COMA
K7211	CHRONIC HEPATIC FAILURE WITH COMA
K7290	HEPATIC FAILURE, UNSPECIFIED WITHOUT COMA
K7291	HEPATIC FAILURE, UNSPECIFIED WITH COMA
K730	CHRONIC PERSISTENT HEPATITIS, NOT ELSEWHERE CLASSIFIED
K731	CHRONIC LOBULAR HEPATITIS, NOT ELSEWHERE CLASSIFIED
K732	CHRONIC ACTIVE HEPATITIS, NOT ELSEWHERE CLASSIFIED
K738	OTHER CHRONIC HEPATITIS, NOT ELSEWHERE CLASSIFIED
K739	CHRONIC HEPATITIS, UNSPECIFIED
K740	HEPATIC FIBROSIS
K741	HEPATIC SCLEROSIS
K742	HEPATIC FIBROSIS WITH HEPATIC SCLEROSIS
K743	PRIMARY BILIARY CIRRHOSIS
K744	SECONDARY BILIARY CIRRHOSIS
K745	BILIARY CIRRHOSIS, UNSPECIFIED
K7460	UNSPECIFIED CIRRHOSIS OF LIVER
K7469	OTHER CIRRHOSIS OF LIVER
K750	ABSCESS OF LIVER
K751	PHLEBITIS OF PORTAL VEIN

Severe Renal Impairment or Mild to Moderate Hepatic Impairment	
ICD-10 Code	Description
K752	NONSPECIFIC REACTIVE HEPATITIS
K753	GRANULOMATOUS HEPATITIS, NOT ELSEWHERE CLASSIFIED
K754	AUTOIMMUNE HEPATITIS
K7581	NONALCOHOLIC STEATOHEPATITIS (NASH)
K7589	OTHER SPECIFIED INFLAMMATORY LIVER DISEASES
K759	INFLAMMATORY LIVER DISEASE, UNSPECIFIED
K761	CHRONIC PASSIVE CONGESTION OF LIVER
K763	INFARCTION OF LIVER
K7689	OTHER SPECIFIED DISEASES OF LIVER
K769	LIVER DISEASE, UNSPECIFIED
K77	LIVER DISORDERS IN DISEASES CLASSIFIED ELSEWHERE
N184	CHRONIC KIDNEY DISEASE, STAGE 4 (SEVERE)
N185	CHRONIC KIDNEY DISEASE, STAGE 5



Lupus Agent

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2021. Available at <http://www.clinicalpharmacology.com>. Accessed on October 22, 2021.
2. 2021 ICD-10-CM Diagnosis Codes. Available at <http://www.icd10data.com/>. Accessed on October 22, 2021.
3. Benlysta Prescribing Information. Philadelphia, PA. GlaxoSmithKline LLC. March 2021.
4. Lupkynis Prescribing Information. Rockville, MD> Aurinia Pharma U.S., Inc. January 2021.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
10/22/2021	Initial publication and presentation to the DUR Board