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Eldersburg Arthritis, LLC 6190 Georgetown Blvd. Eldersburg, MD 21784 410-795-9700 Fax: 410-795-7500

Florin Niculescu, MD, PhD Teodora Niculescu, MD, PhD Betharry Six, CRNP

FAX COVER SHEET

Date: 6/1/21
To: WHC appeals dept.
Fax #: 801-938-2100
Attn: urgent.
Number of pages:(including cover sheet)
REMARKS/COMMENTS '
prease see attached clinicals and copy of Manyland step Therapy Law. Pt. has been on Remirade infusions usince 2009 and in the presenters professional judgement, lemicable is effective in teating the pt's conduction of vheumatoral arthintis please continue to approve permicade infusions in the providers of fice. An interruption in therapy would be harmful to the patrent. Thankyou signed: Mellose Mollinger.
○

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THE MARYLAND STEPTHERAPY LAW

Commercial payers have processes for exceptions

Step Therapy Maryland House Bill (1233) 2014 Session

§ 15-142 (a) (3) Establishment of a step therapy protocol:

Step therapy or fail-first protocol" means a protocol established by an insurer, a nonprofit health service plan, or a health maintenance organization that requires a prescription drug or sequence of prescription drugs to be used by an insured or an enrollee before a prescription drug ordered by a prescriber for the insured or the enrollee is covered.

§ 15–142 (c) Step therapy override process:

When therapy or protocol prohibited. --

An entity subject to this section may not impose a step therapy or fail-first protocol on an insured or an a enrollee it:

- (1) the step therapy drug has not been approved by the U.S. Food and Drug Administration for the medical condition being treated; or
- (2) a prescriber provides supporting medical information to the entity that a prescription drug covered by the entity:
 - (i) was ordered by a prescriber for the insured or enrollee within the past 180 days; and
 - (ii) based on the professional judgment of the prescriber, was effective in treating the insured's or enrollee's disease or medical condition.



Under the process, there is a basis for the exception request

§ 15–142 (e) of the insurance law

- (c) Exception Appendity subject to this section may not impose a step therapy or fall-first protocol on a community subject to this section in a procedure the talk of Foodband Orug Administration its
 - (1) the prescription drug is used to treat the insured's or enrollee's stage four advanced metastatic cancer
 - (2) use of the prescription drug is:
 - (i) consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium Indication for the treatment of stage four advanced metastatic cancer; and
 - (ii) supported by peer-reviewed medical literature.

This document is presented for informational purposes only. This information is not a guarantee of coverage or payment, not intended to provide reimbursement by any payer. Actual benefits are determined by each plan administrator in accordance with its respective policy and procedures, Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as quirent or comprehensive when you view it. Please contact the plan for more information about coverage or any restrictions or prerequisites that may apply. We strongly recommend that you consult the payer organization for its reimbursement policies. All information is subject to change.





THE MARYLAND STEP THERAPY LAW (cont.d)

And a process for granting the exception

§ 15-142. Step therapy or fail-first protocol

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- (i) apaic cambroman entity subjectito this section for an insured or an entitle is:
 (ii) appropriate vice cord that documents that a presonne document document document document documents that a presonne document document
- (III) e near romancim mutually admeed on to varientity subject to this section and the
- (d) Coverage: --
- Subsection (c) of this section may not be construed to require coverage for a prescription drug that is not:
 - (1) covered by the policy or contract of an entity subject to this section; or
 - (2) otherwise required by law to be covered.
- D. On or before July 1, 2015, a payor that requires a step therapy or fail-first protocol shall:*
 - (1) Establish and shall thereafter maintain an online process to allow a prescriber to override the step therapy or fail-first protocol if:
 - (a) The step therapy drug has not been approved by the U.S. Food and Drug Administration for the medical condition being treated; or
 - (b) A prescriber provides supporting medical information to the payor that a prescription drug covered by the payor:
 - (i) Was ordered by the prescriber for the insured or enrolled within the past 180 days; and
 - (ii) Based on the professional judgment of the prescriber, was effective in treating the insured's or enrollee's disease or medical condition;
 - (2) Provide notice to prescribers regarding the availability of its online process; and
 - (3) Provide information to insureds or enrollees on the availability of the step therapy or fall-first protocol within its network.

Source: Md. Code Ann., Ins. 6 15-142 (LexisNexis, Lexis Advance through legislation effective November 6, 2020)

Section source: http://www.dsd.state.md.us/comar/comarhtml/10/10.25:17.03.htm



STATE OF MARYLAND NON-MEDICAL SWITCHING (NMS) PROTECTIONS

Article - Insurance 15-831

SESTION CAND BENEFURINGER ENACTED That this Advishall take effect Octoberal, 2019

- (c) Each entity subject to this section that limits its coverage of prescription drugs or devices to those in a formulary shall establish and implement a procedure by which a member may:
 - (1) receive a prescription drug or device that is not in the entity's formulary or has been removed from the entity's formulary in accordance with this section; or
 - (2) continue the same cost sharing requirements if the entity has moved the prescription drug or device to a higher deductible, copayment, or coinsurance tier.
- (d) The procedure shall provide for coverage for a prescription drug or device in accordance with subsection (c) of this section (f, in the judgment of the authorized prescriber:
 - (I) there is no equivalent prescription drug or device in the entity's formulary in a lower tier;
 - (2) an equivalent prescription drug or device in the entity's formulary in a lower tier:
 - (i) has been ineffective in treating the disease or condition of the member; or
 - (ii) has caused or is likely to cause an adverse reaction or other harm to the member:
- (f) An entity subject to this section that removes a drug from its formulary or moves a prescription drug or device to a benefit tier that requires a member to pay a higher deductible, copayment, or coinsurance amount for the prescription drug or device shall provide a member who is currently on the prescription drug or device and the member's healthcare provider with:
 - (1) Notice of the change at least 30 days before the change is implemented; and
 - (2) In the notice required under item (1) of this subsection, the process for requesting an exemption through the procedure adopted in accordance with this section.

Source: http://mgaleg.maryland.gov/2019RS/chapters_noin/Ch_504_sb0405T.pdf

(Page 7 of 17)

From: 4107957500

Page: 5/15

Date: 6/1/2021 4:20:41 PM

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Buchanan, Brenda, Female DOB: 01/22/1961

Rheumatology Progress Note

Patient: Brenda Buchanan

Physician/Provider: Teodora Niculescu (002)

Date: 04/22/2021

Office: Eldersburg Arthritis, LLC

Established Patient Visit

Chief Complaint and History of Present Illness

Brenda is a 60y old Female who presents with a primary complaint of

SERONEGATIVÉ RA F/U

Painful left knee with swelling

Painful right groin Painful right buttock

Mouth ulcers on MTX

Here for the treatment with Remicade

History of Present Illness:

Brenda c/o painful right buttock, right lower back sometimes radiating down the right leg lateral thigh. Has moderate pain in the right groin with standing, walking in the grocery store, or standing with cooking. Pain does not wake her up at night but she takes one Benadryl to sleep. Has pain in the left knee with swelling. Last steroid injection in this joint did help a lot. Takes 2 Aleves bid.

Past Medical History

High Blood Pressure

Neurological Disease: depression, anxiety

Hyperlipidemia

Respiratory Disease: Hx of asthma - in remission

Gastrointestinal Disease: GERD, iritable bowel syndrome

Arthritis: INFLAMMATORY OA; SERONEGATIVE RA;

Anemia:

Hx of Shingles 2012.

Past Surgical History

Joint Surgery: (L) shoulder RCT repair 2x, (R) big toe surgery due to infection.

Evelid lift

Wisdom teeth extraction

Medications

No changes

Active Medications

Cardizem CD 240 mg capsule, extended release. Take by mouth daily DAILY. Do not substitute.

- diciplenac 1 % topical gel. Take 1 application apply on the skin four times a day QID for 90 days. Dispense 1 and allow for 3 refills.
- Centrum Silver tablet. Take by mouth daily DAILY. Do not substitute.
- losartan 50 mg tablet. Take by mouth daily DAILY. Do not substitute.
- . cholecalciferol (vitamin D3) 50 mcg (2,000 unit) capsule. Take by mouth daily DAILY. Do not substitute.
- fluoketine 40 mg capsule. Take by mouth daily DAILY. Do not substitute.
- folid acid 1 mg tablet. Take tablets by mouth Add'l Sig. Dispense 90 and allow for 1 refills. TAKE 1 TABLET DAILY

(Page 8 of 17)

From: 4107957500

Page: 6/15

Date: 6/1/2021 4:20:41 PM

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Buchanan, Brenda, Female DOB: 01/22/1961

TAKE 1 TABLET DAILY.

- hydroxychloroquine 200 mg tablet. Take Add'l Sig. Dispense 180 and allow for 2 refilis. TAKE 1 TABLET TWICE A DAY TAKE 1 TABLET TWICE A DAY.
- sulfasalazine 500 mg tablet. Take 2 tablets by mouth twice a day BID for 90 days. Dispense 360 and allow for 3 refills. Do not substitute. TAKE 1 TO 2 TABS BY MOUTH TWICE A DAY TAKE 1 TO 2 TABS BY MOUTH TWICE A DAY.
- methotrexate sodium 2.5 mg tablet. Take tablets Add'l Sig. Dispense 96 and allow for 3 refills. TAKE 8 TABLETS ALL AT ONCE BY MOUTH ONCE WEEKLY.
- Remicade 100 mg intravenous solution.

<u>Systems Review</u>

Constitutional Symptoms: none

Cardiovascular Symptoms: • swelling in legs or feet

Respiratory Symptoms: none

Gastfointestinal Symptoms: none

Urinary Symptoms: none

Musquioskeletal Symptoms: • muscle pain • joint pain • joint swelling • back pain • joint stiffness

Skin Symptoms: none

All other systems were reviewed and are negative.

Physical Exam Added vitals entry: Measurement date: 2019-07-25 10:16 Weight: 170.0 lbs Height: 5 ft 1.0 in BMI: 32.1 Heart rate: 78 bpm Blood pressure: 110 / 77 mmHg

Constitutional: is Normal.

HEENT: Neck is Normal. Lymph Nodes are Normal. Respiratory: Chest Wall is Normal. Lungs are Normal.

Cardiovascular: S1 and S2 Normal. Heart has regular rhythm. Heart does not have murmur.

Gastrointestinal: Abdomen is normal.

Neurological:

Vascular/Circulation: Edema Abnormal. 0.5 leg edema pre-tibial

Skin: Skin is Normal. Lymphatic: is Normal.

Psychiatric:

Musculoskeletal Exam

<u>Upper Extremities</u>

Shoulder is Abnormal: stiffness on the left.

Elbow is Normal, on the right and left.

Wrist is Normal.

Hand is Normal.

MCP's are Normal.

PIP's are Normal, stiffness on flexion

DIP's are Normal, on the right and left.

Lower Extremities

Hip is Abnormal: Tenderness, Stiffness Painful and decreased ER on the right.

Knee is Abnormal: swelling discomfort on flexion Bakers cyst on the left.

Ankle is Normal, on the right and left.

Midfoot is Normal.

(Page 9 of 17)

From: 4107957500

Page: 7/15

Date: 6/1/2021 4:20:41 PM

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Buchanan, Brenda, Female DOB: 01/22/1961
MTP's are Normal, on the right and left.

<u>Entheses</u>

Trochanteric Bursae are Abnormal: Tenderness mild on the right.
Anserine Bursae are Abnormal: Swelling Tenderness on the left.
Achilles Tendon is Normal.
Plantar Fascia is Normal.

<u>Other</u>

C Spihe is Normal.

L Spine is Abnormal: Stiffness. Scoliosis T-Spine is Normal.

Muscles are Abnormal: Tender on the right buttock.

Imaging & Diagnostic Studies

MIPS 2021

BMI high - with intervention (nutrition counseling, exercise counseling) - HIGH - START DIET TB prevention if + and on a biologic - N/A

CDAI 16 MA

MHAQ 4/30

DMARD MTX, HCQ; SSZ;

Biologics - REMICADE

Steroids no

Disease Prognosis (ESR, CRP, RF, CCP, Sjogrens, Erosions, Nodules, other organ involvement) - POOR

Needs shingles vaccine

No preumococcal vaccine - needs early

Quantiferon done yearly

Impression & Diagnosis

Brenda is here to have the tx for sero-hegative RA with Remicade

Painful swollen left knee with Bakers cyst interfering with her walking

Right hip painful OA with pain in the groin and right SI enthesis painful Mouth ulcers maybe from MTX – will increase Folic Acid to 2 mg qd

Mild stiffness left RCT s/p repair

Anemia in the past - now ok, will watch.

On Ca/D for bone protection.

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Plan of Treatment

Notes on Medications and/or Plan of Treatment/Diagnosis: Addendum: 6/1/21: stretching exercises for back pain provided. Use local heat. Might MRI if not better. Meloxicam 15 mg qd helps.

Remicade infused and tolerated well.

Right SI enthesis injected with steroids to help pain and inflammation. Risks and benefits of procedure were discussed with patient. Injection administered on the right SI entheses. To help with the local inflammation and pain. Sterile preparation performed with alcohol prep pads. Local anesthesia performed with Ethyl Chloride spray. The patient was injected with Depomedrol 40mg mixed with Lidocaine 1% in the dorsal aspect of right SI entheses. Patient tolerated procedure well. The patient was advised to apply ice next 2 days every 2-3 hours for severe pain in the injected/aspirated joint/bursa.

L knee injected with steroids to help pain and inflammation. Risks and benefits of procedure were discussed with patient. Injection administered on the left knee to help with the local inflammation and pain. Sterile preparation performed with Betadine. Local anesthesia performed with Ethyl Chloride spray. The patient was injected with Depomedrol 40mg mixed with Lidocaine 1% in the anterior and lateral aspect of the left knee. Patient tolerated procedure well. The patient was advised to apply ice next 2 days every 2-3 hours for severe pain in the injected/aspirated joint/bursa.

Start Meloxicam 15 mg qd instead of Aleve 4 daily. ERX.

Might need MRI L spine and right hip.

Continue stretching exercises for the lower back, SI's and hips.

Advised to continue:

\$52 500 mg 2 pills bid.

MTX 20 mg po q week. Splits dose 4 and 4.

Folic Acid I mg po q day. Increase to 2 mg qd due to mouth ulcers.

HCQ 200 mg bld. Dose is safe per the 5 mg/kg/day dosing guidelines. Reminded eye exam is needed annually to monitor for HCQ toxicity. She reports it was done in 2020. Referred again 4/22/21.

Continue the Calcium and Vitamin D daily: 1,200 mg of Ca and 1,000 units of Vitamin D3. Calcium can come through diet 350 mg of Ca per portion of foods rich in Ca: broccoli, yogurt, cheese, milk, etc.

Repeat CBC, CMP, ESR, CRP every 4 months to monitor medication toxicities. Labs 03/2021 WNL CBC, CMP, ESR, CRP. DW pt.

Eye exam r/o HCQ tox overdue, referral provided to go now.

Regards,

Teodora M. Niculescu, M.D.

Procedure Date: 04/22/2021 Printed Date: 06/01/2021

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Buchanan, Brenda, Female DOB: 01/22/1961

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(Page 12 of 17)

From: 4107957500

Page: 10/15

Date: 6/1/2021 4:20:41 PM

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Buchanan, Brenda, Female DOB: 01/22/1961

Rheumatology Progress Note

Patient: Brenda Buchanan

Physician/Provider: Florin Niculescu (001)

Date: 12/14/2020

Office: Eldersburg Arthritis, LLC

Established Patient Visit

Chief Complaint and History of Present Illness

Brenda is a 59y old Female who presents with a primary complaint of SERONEGATIVE RA F/U

Here for the treatment with Remicade Patient doing well on current treatment

History of Present Illness:

PT IS 59 Y/O WF WITH H/O SERONEGATIVE RAUNDER CONTROL WITH REMICADE AND DMARDS.

PT HAS TODAY COMPLAINS OF STIFF PAINFUL HANDS WITH SYNOVITIS.

No more pain in the HIPS AND KNEES.

She reports stiffness for 20 min in the morning.

No leg numbness. No stool or urine incontinence.

Her energy level is stable. No cough. No diarrhea.

No headache. No infusion reactions.

Mouth ulcers absent. No nausea. No skin rash.

Past Medical History

High Blood Pressure

Neurological Disease: depression, anxiety

Hyperlipidemia

Respiratory Disease: Hx of asthma - in remission

Gastrbintestinal Disease: GERD, iritable bowel syndrome

Arthritis: INFLAMMATORY OA; SERONEGATIVE RA;

Anemia:

Hx of Shingles 2012.

Past Surgical History

Joint Surgery: (L) shoulder RCT repair 2x, (R) big toe surgery due to infection.

Evelid lift

Wisdom teeth extraction

Family History

No FHX of Psoriasis, Rheumatoid Arthritis, Gout, Lupus, Colitis.

Buchanan, Brenda, Female DOB: 01/22/1961

Social History

Patient does not consume alcohol.

Patient does not consume tobacco.

Patient is employed:

Patient drinks caffeinated beverages.

Patient does not use drugs for reasons that are not medical.

Patient exercises regularly.

Patient gets enough sleep at night.

Patient wakes up feeling rested.

Patient is married.

Allergies:

No changes

No Active Allergies

Medications

Performed Reconciliation

Active Medications

- Cardizem CD 240 mg capsule, extended release. Take by mouth daily DAILY. Do not substitute.
- sulfasalazine 500 mg tablet. Take Add'l Sig. Dispense 360 and allow for 3 refills. TAKE 1 TO 2 TABLETS TWICE ADAY TAKE 1 TO 2 TABLETS TWICE ADAY.
- dicipfenac 1 % topical gel. Take 1 application apply on the skin four times a day QID for 90 days. Dispense 1 and allow for 3 refills.
- Centrum Silver tablet. Take by mouth daily DAILY. Do not substitute.
- methotrexate sodium 2.5 mg tablet. Take 8 tablets by mouth weekly Q1wk for 90 days. Dispense 96 and allow for 1 refills. Do not substitute.
- losartan 50 mg tablet. Take by mouth daily DAILY. Do not substitute.
- cholecalciferol (vitamin D3) 50 mcg (2,000 unit) capsule. Take by mouth daily DAILY. Do not substitute.
- fluoketine 40 mg capsule. Take by mouth daily DAILY. Do not substitute.
- folio acid 1 mg tablet. Take tablets by mouth Add'l Sig. Dispense 90 and allow for 1 refills. TAKE 1 TABLET DAILY TAKE 1 TABLET DAILY.
- sulfasalazine 500 mg tablet. Take Add'l Sig. Dispense 360. TAKE 1 TO 2 TABS BY MOUTH TWICE A DAY TAKE 1 TO 2 TABS BY MOUTH TWICE A DAY.
- hydroxychloroquine 200 mg tablet. Take Add'l Sig. Dispense 180 and allow for 2 refills. TAKE 1 TABLET TWICE A DAY TAKE 1 TABLET TWICE A DAY.
- methotrexate sodium 2.5 mg tablet. Take tablets Add'l Sig. Dispense 96 and allow for 3 refills. TAKE 8 TABLETS ALL AT ONCE BY MOUTH ONCE WEEKLY TAKE 8 TABLETS ALL AT ONCE BY MOUTH ONCE WEEKLY.
- sulfasalazine 500 mg tablet. Take 2 tablets by mouth twice a day BID for 90 days. Dispense 360 and allow for 3 refills. Do not substitute. TAKE 1 TO 2 TABS BY MOUTH TWICE A DAY TAKE 1 TO 2 TABS BY MOUTH TWICE A DAY.

Systems Review

Constitutional Symptoms: none

Eyes Symptoms: none ENT Symptoms: none

Cardiovascular Symptoms: none Respiratory Symptoms: none Gastrointestinal Symptoms: none

Urinary Symptoms: none

Musculoskeletal Symptoms: • joint pain • joint swelling • joint stiffness

Procedure Date: 12/14/2020 Printed Date: 06/01/2021

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From: 4107957500

Page: 12/15

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Buchanan, Brenda, Female DOB: 01/22/1961

Skin Symptoms: none

All other systems were reviewed and are negative.

Physical Exam Added vitals entry: Measurement date: 2019-07-25 10:16 Weight: 170.0 lbs Height: 5 ft 1.0 in BMI: 32.1 Heart rate: 78 bpm Blood pressure: 110 / 77 mmHg

Constitutional: is Normal.

HEENT: Mouth/Throat is Normal. Neck is Normal. Lymph Nodes are Normal.

Respiratory: Chest Wall is Normal. Lungs are Normal.

Cardiovascular: S1 and S2 Normal. Heart has regular rhythm. Heart does not have murmur.

Gastrointestinal: Abdomen is normal.

Neurological:

Skin: Skin is Normal.

Lymphatic: Psychiatric:

Musculoskeletal Exam

<u>Upper Extremities</u>

Shoulder is Normal. on the right and left.

Elbow is Normal, on the right and left.

Wrist is Abnormal: puffy, tenderness, pain on ROM on the left.

Hand is Abnormal: Swelling, tenderness, on the left.

MCP's are Normal.

PIP's are Abnormal: decreased flexion of all fingers on the left.

DIP's are Normal, on the right and left.

Lower Extremities

Hip is Abnormal: Tenderness, Stiffness decreased ROM on the right.

Knee is Abnormal: mild swelling discomfort on flexion Bakers cyst on the left. L

Ankle is Normal, on the right and left.

Midfobt is Normal.

MTP's are Normal, on the right and left.

Entheses

Trochanteric Bursae are Abnormal: Tenderness mild on the right.

Anserine Bursae are Abnormal: Swelling Tenderness on the left.

Achilles Tendon is Normal.

Plantar Fascia is Normal.

Other

C Spirle is Normal.

L Spine is Abnormal: Stiffness.

T-Spine is Normal.

Muscles are Abnormal: Tender on the right buttock.

Imaging & Diagnostic Studies

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Buchanan, Brenda, Female DOB: 01/22/1961

MIPS 2020

BMI High - with intervention (nutrition counseling, exercise counseling) - HIGH - START DIET

VAS of pain 3/10 and intervention (PT, pain management, anti-inflammatories)

TB screening - NEGATIVE

TB prevention if + and on a biologic - N/A

CDAI 16 MA

RAPID 3 MS 10.5

MHAQ 4/30

DMARD MTX. HCQ; SSZ;

Biologics - REMICADE

Sterolds (<10 < 6mo); (>10 > 6 mo); other reasons than RA -10 MG PREDNISONE PRN.

Disease Prognosis (ESR, CRP, RF, CCP, Sjogrens, Erosions, Nodules, other organ involvement) - POOR

Needs shingles vaccine

No prieumococcal vaccine - needs early

Quantiferon done.

Impression & Diagnosis

Brenda is here to have the tx for

sero-negative RA with Remicade - doing mostly well.

Painful swollen left hand and fingers after a recent injury - much improved

Left knee with Baker's cyst swollen, tender - less severe

Left Anserine bursitis swollen tender

Left calf larger not tender - per pt "always a little larger than the right one" - might do a Doppler US - pt declined at this point - improved

Right hip and SI enthesis both painful with decreased ROM R hip

Following with Ortho for (L) hand/wrist injury fx vs sprain ?? Needs to re-xray on 5/18/20. Had fall with injury on 5/4/20, wrist was too swollen to see what is truly going on, has splint in place.

Anemia in the past - now ok, will watch.

On Ca/D for bone protection.

Plan of Treatment

Notes on Medications and/or Plan of Treatment/Diagnosis:

Remidade infused and tolerated well.

Advised decrease intensity of physical activity which seems to irritate the left knee.

Referred for xrays of both hips suspect some more degeneration on the right.

Reviewed with pt stretching exercises for the lower back, Si's and hips.

Adviséd to continue:

SSZ 500 mg 2 pills bid.

MTX 20 mg po q week. Splits dose 4 and 4.

Folic Acid 1 mg po q day.

Buchahan, Brenda, Female DOB: 01/22/1961

HCQ 200 mg bid. Dose is safe per the 5 mg/kg/day dosing guidelines. Reminded eye exam is needed annually to monitor for HCQ toxicity. She reports it was done in 2020.

Continue use NSAIDS prn when joint pain is worse. For now 2 Ibuprofen qhs.

Continue the Calcium and Vitamin D daily: 1,200 mg of Ca and 1,000 units of Vitamin D3. Calcium can come through diet 350 mg of Ca per portion of foods rich in Ca: broccoli, yogurt, cheese, milk, etc.

Repeat CBC, CMP, ESR, CRP every 4 months to monitor medication toxicities. Due again in July 2020.

Had eye exam in 11/2019 - note in chart.

Did return to eye office in early 2020 for HCQ OCT and VF but no note in chart.

Pt reports this was done.

Labs from 3/2020 reviewed with pt - all normal and negative for DMARD toxicities and/or inflammation. Drawn today again.

Next Appointment in 6 weeks.

Regards.

Florin I. Niculescu, M.D.

Regards,

Teodora M. Niculescu, M.D.

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Procedure Date: 12/14/2020 Printed Date: 06/01/2021

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Buchahan, Brenda, Female DOB: 01/22/1961