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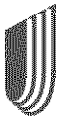

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To: Commercial Employer & Individual
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From: UHC Medicare Expedited Appeals
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NOTES:

Date and time of transmission: Tuesday, May 4, 2021 10:44:54 AM
Number of pages including this cover sheet: 12

UC DAVIS HEALTH

FAX COVER SHEET

TO: United Healthcare Appeals Dept **Date: 03May2021**

PHONE: 877.842.3210 **Time: ~~1140~~ 1425 PD**

FAX: 877.960.8235 **# pages: 11 (including cover)**

SUBJ: Ref Call # 3712

Re: N. Spring
DOB: 01/14/1998
Member ID: 966864434
Reference: A122152489

Mary Burns, RN, BSN
UC Davis Specialty Clinics-Department of Gastroenterology & Hepatology
Midtown Ambulatory Care Clinic
3160 Folsom Boulevard, Suites 3500 & 3600, Sacramento, California 95816
(P) 916 734-8616
(F) 916 451-3032

UC DAVIS HEALTH

MIDTOWN GASTROENTEROLOGY

3160 FOLSOM BLVD, SUITE 3600
SACRAMENTO CA 95816-5270

April 29, 2021

Re: Letter of Medical Necessity for Stelara Re-Induction

Patient: Nicole Spring
DOB: 1/14/1998
Member ID: 966864434
Reference: A122152489
Diagnosis: Crohn's Disease

To whom it may concern,

We are writing on behalf of our patient, Nicole Spring to appeal the recent denial for her Stelara (ustekinumab) therapy. This letter serves to document the patient's medical need for re-induction with ustekinumab as prescribed. In this letter, you will find (1) patient's medical history and (2) literature supporting the use of Stelara re-induction.

Ms. Spring is a 23-year-old patient diagnosed with Crohn's colitis after presenting with abdominal pain and diarrhea in 2003 but did not receive therapy until her diagnosis was confirmed by colonoscopy in 2019. She had been prescribed budesonide for three weeks but discontinued the medication due to intolerance (acne and fatigue). In September 2020, she was started on ustekinumab to which she responded well, achieving clinical remission. We repeated a colonoscopy in April 2021 to re-stage her disease, however, she was noted to have active inflammation (SES-CD 7) in the right colon. Her C. difficile test was negative. Most recently, patient reported worsened symptoms of intermittent stomach aches, increase in frequency of bowel movements and urgency. She has also lost about 8-9 lbs. Ms. Spring has high-risk disease due to her young age at diagnosis (<30 years).

We understand that the FDA approved dose of ustekinumab for Crohn's disease is an induction infusion at initiation of therapy, followed by 90 mg every 8 weeks. However, use of off-label dosing has proven to be both safe and effective in several clinical instances. Battat et al presented that optimizing ustekinumab trough levels will augment therapy through improved clinical and endoscopic response.[1] In patients that do not achieve adequate drug concentrations, re-induction can provide an opportunity for therapy optimization. Park and colleagues provide a case series report of re-inducing using a 6 mg/kg dose in patients with moderate to severe Crohn's disease.[2-3] All patients in the report had tried one or more anti-TNF agents and/or vedolizumab before being switched to ustekinumab. After failing initial therapy or only experiencing partial response, patients were provided with a re-induction dose, which showed improvements in symptom control and in endoscopic disease activity. Post-re-induction, patients were also able to wean off steroids using a traditional taper, reducing long-term steroid exposure.

The clinical references above show that re-induction of ustekinumab is clinically efficacious and often necessary in Crohn's patients who are losing initial response to therapy. As noted, Ms. Spring's repeat colonoscopy revealed evidence of active inflammation in the right colon on standard dosing ustekinumab, but clinically she has experienced secondary loss of response. Given Ms. Spring's high-risk disease and demonstrated initial response to ustekinumab, the most conservative approach would be to optimize this medication by re-inducing and dose escalating. Together with the literature and our collective experiences, we believe re-induction is indeed necessary for the successful management of Ms. Spring's Crohn's disease.

We hope you will consider the information provided and approve our patient's ustekinumab re-induction therapy. We would be happy to discuss any questions or concerns you may have. Thank you for your time and consideration.

Sincerely,

Eric Mao, M.D.
Anh-Thu Truong, Pharm.D.

UC Davis Health
Gastroenterology
P: (916) 734-0900 option #5
F: (916) 703-5509

References:

1. Battat R ,Kopylov U ,Bessissow T et al. Association between ustekinumab trough concentrations and clinical, biomarker, and endoscopic outcomes in patients with Crohn's disease. *Clin Gastroenterol Hepatol*. 2017;9:1427-34.
2. Park S, Evans E, Sandborn WJ, Boland B. Ustekinumab IV 6 mg/kg loading dose re-induction improves clinical and endoscopic response in Crohn's disease: a case series. Am J Gastroenterol. 2018;113(4):627-629. doi: 10.1038/ajg2018.22.
3. Ma C ,Fedorak RN ,Kaplan GG et al. Long-term maintenance of clinical, endoscopic, and radiographic response to ustekinumab in moderate to-severe Crohn's disease: real-world experience from a multicenter cohort study. *Inflamm Bowel Dis*. 2017;23:833-9.

Referral Summary

Referral#: 8700987

Member Information

Name:	**Nicole Spring**
MRN:	1671200
DOB:	01/14/1998
Address:	4741 Gresham Drive El Dorado Hills CA 95762
Phone #:	916-402-2140 (home) 916-221-2258 (work), Telephone Information: Mobile 916-221-2258
Subscriber ID#	966864434
Payor:	UNITED HEALTHCARE

Referred to Information

Provider:	
Department:	Adult IV Infusion Center
Specialty:	Infusion Clinic
Address:	2279 45th Street Sacramento CA 95817-1514
Phone #:	916-734-5959

Referred by Information

Provider:	Eric Ji-Yuan Mao
Department:	Midtown Gastroenterology
Address:	3160 Folsom Blvd, Suite 3500 Sacramento CA 95816-5270
Phone #:	916-734-8616

Referral Information

Priority:	Urgent	**Type:**	Treatment Plan (Beacon) / Therapy Plan
Status:	Denied	**Auth #:**	
Start Date:	04/21/2021	**End Date:**	No expiration date on the referral.
Authorized Visits:		0	

Diagnoses:
K50.80 (ICD-10-CM) - Crohn's disease of both small and large intestine without complication (HCC)
st

Procedures:
J3358 - PR USTEKINUMAB, IV INJECT, 1 MG
USTEKINUMAB INDUCTION IV

Provider Not in System Note if Applicable

No notes of specified type found.

Appointment Information

No associated appointments

Spring, Nicole

MRN: 1671200

9102112416836

Telemedicine Scheduled
4/27/2021
Midtown Gastroenterology

Provider: Mao, Eric Ji-Yuan, MD (GASTROENTEROLOGY)
Primary diagnosis: Crohn's disease of both small and large intestine without complication (HCC)
Reason for Visit: Follow Up With Specialist; Referred by Grant, Kevin Eugene

Visit Date

Progress Notes

Louie, Justin Shi-Wei, MD (*PHYSICIAN: FELLOW) - GASTROENTEROLOGY

Video Visit Note

I performed this clinical encounter by utilizing a real time telehealth video connection between my location and the patient's location. The patient's location was confirmed during this visit. I obtained verbal consent from the patient to perform this clinical encounter utilizing video and prepared the patient by answering any questions they had about the telehealth interaction.

CHIEF COMPLAINT: Nicole Spring is a 23yr female seen for a follow-up visit consultation for Crohn's disease at the request of Grant, Kevin Eugene.

History of Present Illness
This is a 23yr female with a history of ileocolonic Crohn's disease diagnosed in 2003. She had been treated with budesonide (intolerance due to acne and fatigue). She is currently on ustekinumab (started 9/28/20) every 8 weeks. She presents for follow-up.

IBD History:
She was diagnosed in 2003 with Crohn's colitis but she does not recall taking any therapy due to uncertainty of diangosis. She developed abdominal pain and diarrhea while in Capetown in 2019 so she saw GI in NYC on return and underwent colonoscopy 8/2019 diagnosed Crohn's disease. She subsequently moved to RI and established care with Dr. Fine at Brown University. Colonoscopy in 2/2020 confirmed Crohn's disease. She started budesonide for 3 weeks but led to acne and fatigue so it was stopped. In the interim, patient moved to Sacramento due to COVID. Patient started stelara on 9/28/20.

She was last seen on TAV 12/8/20. At that time she was in clinical remission and was continued on Ustekinumab. Re-staging colonoscopy 4/14/21 noted active SES-CD 7 disease in the Right colon. Plan was for to request re-induction and dose-escalation to q4 wk dosing; still pending authorization

Today:
Pt currently feeling overall well; but has been having some worsened symptoms for the last few days since Sunday. Overall feeling a little bit worse compared to last visit. Intermittent stomach aches, usually about a 3/10; since this Sunday has increased to 6/10. Pt normally moves her bowels once or twice a day. This week has been moving >5x a day. Soft stools. No blood. No nocturnal events. Some urgency. Weight has gone down about 8-9 lbs

Last dose of stelara on 3/17. Does not notice any "taper effect" based on timing of her dosages.
- Negative C diff test on 4/14
- Got second dose of the Pfizer vaccine 2 weeks ago

Patient denies nausea, vomiting, diarrhea, constipation, bloody stools, anorexia, heartburn, dysphagia, odynophagia. No f/c/s, rashes, severe joint pains, uveitis.

Patient does not have family planning plans for near future. On OCP.

IBD Summary:

Type: CD
Extent: Ileocolonic
Diagnosis year: 2003
Basis of diagnosis: colonoscopy
Surgery: none
Previous therapy: budesonide, sulfasalazine
Current therapy: Stelara (started 9/28/20)
Last colonoscopy: 4/14/21: SES-CD 7 in Right colon

OBJECTIVE:

Latest UC Davis Labs:

Lab Results

Component	Value	Date
WBC	8.8	12/09/2020
RBC	4.16	12/09/2020
HGB	12.5	12/09/2020
HCT	37.1	12/09/2020
MCV	89.3	12/09/2020
MCH	30.1	12/09/2020
MCHC	33.7	12/09/2020
PLT	266	12/09/2020

Lab Results

Component	Value	Date
ALT	14	12/09/2020
ALT	22	08/03/2006
AST	19	12/09/2020
AST	38	08/03/2006

No results found for: AMY
No components found for: LIPASE, LIPA

Lab Results

Component	Value	Date
CRP	0.3	12/09/2020

Latest Outside Labs: none

Latest imaging and other diagnostics;

Colonoscopy 4/14/21
Findings and Interventions:
1) Rectal Exam: Digital rectal exam did not reveal any masses or strictures.

2) Retroflexion: Normal.

3) Terminal ileum was normal for the examined extent of 10 cm proximal to ileocecal valve. Random biopsies were performed.

4) In the cecum and ascending colon (65cm to 75cm from anal verge), there were scattered, serpiginous ulcerations/erosions ranging in size from 5mm to 2cm. This was biopsied.

5) The exam was otherwise normal.

Simple Endoscopic Score - Crohn's disease

Ileum:
Size of ulcers: none (0)

Ulcerated surface: none (0)
Affected Surface: unaffected (0)
Presence of Narrowings: none (0)

Right colon:
Size of ulcers: Large (0.5-2.0 cm) (2)
Ulcerated surface: >30% (3)
Affected Surface: 50-75% (2)
Presence of Narrowings: none (0)

Transverse colon:
Size of ulcers: none (0)
Ulcerated surface: none (0)
Affected Surface: unaffected (0)
Presence of Narrowings: none (0)

Left colon/Sigmoid:
Size of ulcers: none (0)
Ulcerated surface: none (0)
Affected Surface: unaffected (0)
Presence of Narrowings: none (0)

Rectum:
Size of ulcers: none (0)
Ulcerated surface: none (0)
Affected Surface: unaffected (0)
Presence of Narrowings: none (0)

SES-CD: 7 (0-2 remission, 3-6 mild, 7-15 moderate, >15 severe)

Impression:
1) SES-CD 7
2) This is a 23yr female with a history of ileocolonic Crohn's disease diagnosed in 2003. She had been treated with budesonide (intolerance due to acne and fatigue). She is currently on ustekinumab (started 9/28/20) every 8 weeks with persistent moderately-active endoscopic disease.

Recommendation/Plan:
1) Await pathology.
2) Continue ustekinuamb but we will consider dose escalation.

Report Electronically Signed By: Eric Mao, MD Gastroenterology Attending

A. ILEUM, TERMINAL (BIOPSY):
- **Small bowel mucosa with no significant histopathologic changes**

B. COLON, CECUM (BIOPSY):
- **Chronic colitis with moderate activity**

C. COLON, ASCENDING (BIOPSY):
- **Patchy chronic colitis with at least mild activity**

D. COLON, TRANSVERSE (BIOPSY):
- **Colonic mucosa with no significant histopathologic changes**

E. COLON, DESCENDING (BIOPSY):
- **Colonic mucosa with no significant histopathologic changes**

F. COLON, SIGMOID (BIOPSY):
- **Colonic mucosa with no significant histopathologic changes**

G. RECTUM (BIOPSY):
- **Colonic mucosa with no significant histopathologic changes**

COMMENT:
No viral inclusions, granulomata or dysplasia are seen in any of these biopsies. Findings are compatible with patient's clinical history.

Colonoscopy 2/2020:
-Fentanyl 150mcg IV, versed 9mg IV
-mild erythema in TI
-Diffuse moderate inflamation with altered vascularity, friability, mucus in ascending/cecum
-7mm rectal polyp
-colon otherwise nl

Histology:
A. TI: Ileal mucosa with reactive lymphoid hyperplasia and patchy active inflammation with pinpoint erosions overlying lymphoid follicles compatible with CD in appropriate clinical setting; no granuloma/dysplasia
B. Cecum: patchy active colitis, non-specific
C. Ascending: moderate chronic active colitis variably involving the biopsy fragments with features highly suggestive of CD
D. Transverse: focal active colitis.
E. Descending:focal active colitis.
F. Sigmoid: normal
G. Rectum: normal
H. Rectal polyp: inflammatory polyp, juvenile type, no dysplasia

Colonoscopy 8/29/2019 at 72nd street med associates, Dr. Gil Weitzman
-MAC
-nl transverse, descending, sigmoid, rectum
-ulceration with erythema, loss of vascular tone, edema in continuosu fashion from ascending colon to cecum
- erythema and small ulceration in TI

Impression:
-R-sided colitis (mild-moderate)
-Crohn's disease - mild

Path:
A. Cecum: Mild active chronic colitis
B. Ileum: focal active ileitis, no chronicity
C. R Colon: mild active chronic colitis
D. Transverse: nl
E. L colon: nl
F. Sigmoid: nl
G. Rectum: nl

MR Enterography 8/26/2019:
-no bowel obstruction/dilatation
-TI/ICV nl
-no small bowel inflammatory changes, thickening, or abnormal enhancement
-no ileitis/enteritis
-persistent circumfrential thickening of cecum a/w hyperemia suggestive of R-sided colitis
-minimal focal luminal narrowing in cecum

Impression:
Persistent circumfrential thickening of cecum with associated hyperemia suggestive of R-sided colitis

Impression

ASSESSMENT AND PLAN:
This is a 23yr female with a history of ileocolonic Crohn's disease diagnosed in 2003. She had been treated with budesonide (intolerance due to acne and fatigue). She is currently on ustekinumab (started 9/28/20) q8 weeks. She presents for follow-up with some recurrence of abdominal pain and increased stool frequency.

Patient's Crohn's disease is mildly active with a Harvey-Bradshaw Index of 7. Patient has high-risk disease due to age <30 years at diagnosis. She continued to have evidence of active inflammation in the right colon on standard dosing ustekinumab but clinically she has experienced secondary loss of response.

We recommend escalation of ustekinumab monotherapy to q4 wk dosing with IV re-induction. She has had poor response to budesonide in the past, so will hold off for now. She will need repeat biologic (calprotectin) or endoscopic evaluation after dose escalation to assess response.

Summary of Recommendations:
1. Request ustekinumab IV re-induction and then every 4 weeks maintenance.

2. Check fecal calprotectin. Bloodwork at time of re-induction

3. She will need a re-evaluation (colonoscopy or calprotectin if baseline elevated) in about 4 months after dose escalation.

4. Patient encouraged to optimize preventive care with annual skin exam and cervical cancer screening.

5. Patient to transition care back to Dr. Sean Fine at Brown University as she is moving back to RI at the end of May 2021.

-- As always, the patient was counseled to contact the GI clinic or the after-hours physician on call for any new symptoms or worsening symptoms or complications in the interim between now and the patient's next follow-up visit with our office.

Justin S Louie, MD.
Gastroenterology Fellow, PGY6.
UC Davis Medical Center.

Thank you for the opportunity to take part in the care of this patient. Please do not hesitate to contact me with any questions or concerns.

Approximately 40 minutes were spent with the patient, of which more than 50% of the time was spent in counseling and/or coordinating care on inflammatory bowel disease. The patient understands and agrees with the plan of care outlined.

I saw and evaluated the patient and agree with the Fellow's findings and plan we developed as written.

I spent a total of 40 minutes today on this patient's visit. This included 40 minutes of face to face time, more than 50% of which was spent in counseling or coordinating care, for the following medical problem(s): Crohn's disease. I was involved with the complex medical decision making with my fellow including interpreting imaging studies, endoscopy, laboratory tests, and resolving current therapeutic side effects.

The remainder of the time was spent on review of the patient record (including but not limited to clinical notes, outside records, laboratory and radiographic studies), medical decision-making, and documentation of the visit.

Report electronically signed by:
Eric J. Mao, MD
Assistant Professor
Department of Medicine
Division of Gastroenterology and Hepatology

Other Notes

All notes

Instructions

It was a pleasure seeing you in clinic today. We have summarized our recommendations below:

- We are still awaiting authorization for Stelara re-induction, we will continue to follow up on this.

- We have ordered a stool study. The closest UCD affiliated lab is in Folsom

- You will need a repeat colonoscopy about 3-4 months after we escalate your Stelara dose. This will need to be done with your local provider on the East coast after your move.

-- Sign up for MyChart if you haven't done so yet and contact the GI clinic or the after-hours physician on call for any new symptoms or worsening symptoms or complications in the interim between now and your next follow-up visit with our office.

After Visit Summary (Automatic SnapShot taken 4/27/2021)

Additional Documentation

Vitals: LMP 03/31/2021

Encounter Info: Billing Info, History, Allergies, Detailed Report

Communications

Letter sent to Kevin Eugene Grant and Sean David Fine, MD

Orders Placed

Calprotectin, Fecal SendOut

Medication Changes

As of 4/27/2021 10:00 AM

None

Visit Diagnoses

Crohn's disease of both small and large intestine without complication (HCC) K50.80

9
1
0
2
1
1
2
4
1
6
8
3
6