Santa Clara
Family Health Plan

Santa Clara Family Health Plan

Pharmacy & Therapeutics Committee

December 14, 2017
P&T Committee Member Materials

Santa Clara
Family Health Plan

Regular Meeting of the
Santa Clara County Health Authority d.b.a. Santa Clara Family Health Plan
Pharmacy & Therapeutics Committee
Thursday, December 14, 2017
6:00 PM - 8:00 PM
210 E. Hacienda Avenue Campbell, CA 95008

AGENDA

1.	**Introductions**	Dr. Robertson	6:00	5 min.
2.	**Public Comment** Members of the public may speak to any item not on the agenda; two minutes per speaker. The Committee reserves the right to limit the duration of public comment period to 30 minutes.	Dr. Lin	6:05	5 min.
3.	**Meeting Minutes**			
	Review SCFHP 3Q2017 P&T minutes **Possible Action:** Approve minutes	Dr. Lin	6:10	3 min.
4.	**Informational Updates**			
	a. CMO Health Plan Updates	Dr. Robertson	6:13	5 min.
	b. Prescription Drug Prior Authorization or Step Therapy Exception Request Form (Revised Form 61-211)	Dr. Huynh	6:18	2 min.
	c. Appeals & Grievances	Mr. Breakbill	6:20	5 min.
	Adjourn to Closed Session Pursuant to Welfare and Institutions Code Section 14087.36 (w)			
5.	**Metric & Financial Updates**			
	a. Membership	Dr. Robertson	6:25	2 min.
	b. Pharmacy Dashboard	Dr. Otomo	6:27	5 min.
	c. Drug Utilization & Spend	Dr. McCarty	6:32	10 min.
6.	**Discussion and Recommendations for changes to SCFHP Cal MediConnect Formulary & Prior Authorization Criteria**			
	a. MedImpact 3Q2017 P&T Meetings Minutes	Dr. Huynh	6:42	5 min.
	b. MedImpact 4Q2017 P&T Part D Actions **Possible Action:** Approve MedImpact Minutes & Actions			
	c. SCFHP Part B Prior Authorization Grid **Possible Action:** Approve Part B PA Grid			
7.	**Discussion and Recommendations for Changes to SCFHP Medi-Cal & Healthy Kids Formulary & Prior Authorization Criteria**			

Santa Clara
Family Health Plan

a.	Formulary Modifications	Dr. Otomo	6:47	5 min.
	Possible Action: Approve formulary recommendations			
b.	Prior Authorization Criteria	Dr. Otomo	6:52	10 min.
	1. Hepatitis C – *Update*			
	2. Ciclopirox 8% - *New*			
	3. Non-formulary			
	4. Brand Name			
	5. Off-Label			
	6. Compounded Medications			
	7. General Criteria – UM Medical Drugs			
	8. Eosinophillic Asthma			
	9. Cotellic			
	10. Duragesic			
	11. Emend			
	12. Exelon			
	13. Farydak			
	14. Iressa			
	15. Keytruda			
	16. Lyrica			
	17. Marinol			
	18. Myrbetriq			
	19. Nebupent			
	20. Nexavar			
	21. Odomzo			
	22. Restasis			
	23. Revatio			
	24. Targretin			
	25. Temodar			
	26. Tymlos			
	27. Xarelto			
	28. Xolair			
	29. Zarxio			
	Possible Action: Approve prior authorization criteria			
c.	SCFHP Medical Pharmacy Prior Authorization Grid			
	Possible Action: Approve Medi-Cal PA Grid			
d.	DHCS Medi-Cal CDL Updates & Comparability	Dr. McCarty	7:02	10 min.
	Possible Action: Approve formulary recommendations			
e.	New Drugs and Class Reviews	Dr. McCarty	7:12	30 min.
	1. Shringrix			
	2. Diabetes Update: SGLT-2, GLP-1, DPP-4 inhibitors			
	3. CAR T-Cell Therapies – *informational only*			
	Possible Action: Approve formulary recommendations			

Reconvene in Open Session

Santa Clara
Family Health Plan

8.	**Discussion Items**			
	a. Update on New Drugs and Generic Pipeline	Dr. McCarty	7:42	18 min.
9.	**Adjournment**	Dr. Lin	8:00	
	Next Meeting			

Santa Clara
Family Health Plan

SCFHP 3Q2017 P&T Meeting Minutes

Santa Clara Family Health Plan
SCFHP Pharmacy & Therapeutics Committee 12.14.17

Santa Clara
Family Health Plan

Regular Meeting of the
Santa Clara County Health Authority d.b.a. Santa Clara Family Health Plan
Pharmacy & Therapeutics Committee
Thursday, September 21, 2017
6:00 PM - 8:00 PM
210 E. Hacienda Avenue Campbell, CA 95008

MINUTES

Voting Committee Members	Specialty	Present (Y or N)
Jimmy Lin, MD	Internal Medicine	Y
Hao Bui, BS, PharmD	Community Pharmacy (Walgreens)	Y
Minh Thai, MD	Family Practice	N
Amara Balakrishnan, MD	Pediatrics	Y
Peter Nguyen, MD	Family Practice	Y
Jesse Parashar-Rokicki, MD	Family Practice	Y
Narinder Singh, PharmD	Health System Pharmacy (SCVMC)	N
Ali Alkoraishi, MD	Adult & Child Psychiatry	Y
Dolly Goel, MD	VHP Chief Medical Officer	Y
Xuan Cung, PharmD	Pharmacy Supervisor (VHP)	Y
Johanna Liu, PharmD, MBA	SCFHP Director of Quality and Pharmacy	Y
Jeff Robertson, MD	SCFHP Chief Medical Officer	Y

Non-Voting Committee Members	Specialty	Present (Y or N)
Lily Boris, MD	SCFHP Medical Director	N
Caroline Alexander	SCFHP Administrative Assistant, Medical Management	Y
Christine Tomcala	SCFHP Chief Executive Officer	N
Tami Otomo, PharmD	SCFHP Clinical Pharmacist	Y
Dang Huynh, PharmD	SCFHP Pharmacy Manager	Y
Amy McCarty, PharmD	MedImpact Clinical Program Manager	Y
Darryl Breakbill	SCFHP Grievance and Appeals Manager	Y

	Topic and Discussion	Follow-Up Action
1	**Introductions**	
	The meeting convened at 6:05 PM. Introduced new committee members Dolly Goel, MD and Xuan Cung, PharmD. Dr. Robertson reviewed the Brown Act Meeting requirements with the committee.	
2	**Past Meeting Minutes**	
	The SCFHP 2Q2017 P&T Minutes from June 15, 2017 were reviewed by the Committee as submitted.	Upon motion duly made and seconded, the SCFHP 2Q2017 P&T Minutes from June 15, 2017 were approved as submitted and will be forwarded to the QI

Santa Clara
Family Health Plan

		Committee and Board of Directors.
3	**Public Comment**	
	No public comment.	
4	**Informational Updates**	
	Health Plan Updates Dr. Robertson shared that SCFHP completed a claims system conversion from Xpress to QNXT for all lines of business. Small glitches on claims payments. Received results of DHCS audit. There were two pharmacy related findings (Emergency Prescription Access Monitoring and Denial Notices Member Language). **Membership** Dr. Robertson shared that total membership is currently down to 271,328 members. There has been a slight decrease in membership since June in both Medi-Cal and CMC lines of business. Medi-Cal membership is at 261,702 and CMC is at 7,383. Speculation that the slight drop in membership may be due to concerns regarding immigration. No market forces are impacting membership.	
	Appeals & Grievances Mr. Breakbill presented the Appeals and Grievances report. Small spike around May for Pharmacy Medi-Cal appeals. Average approximately 1700/month. Over half of appeals are upheld. There was a spike in MediCare appeals in May (100 to 120 PA/month). Almost 50% overturned due to submission of additional documentation.	Next report list higher utilized drugs.
	Adjourn to Closed Session Committee adjourned to closed session at 6:25 p.m. to discuss the following items: Pharmacy Dashboard, MTM Oversight (2017Q1 & 2017Q2), Emergency Rx Access Monitoring, Formulary Modifications and Prior Authorization Criteria, New Drugs and Class Reviews, as well as Drug Utilization and Spend Review.	
5	**Pharmacy Dashboard** Dr. Otomo presented the Pharmacy Dashboard for Medi-Cal and CMC. For Medi-Cal, PA volume has been relatively steady from June to August. Above 95% turnaround time for both urgent and standard PAs. For CMC, above 95% turnaround time for both urgent and standard PA's. Prior authorization approval rate for Standard PA's is at 51% and approval rate for Expedited PA's is at 60% as of August. Oversight is done on PBM to make sure following CMS approved criteria. Inter rater reliability is done on prior authorizations. Every individual must pass inter rater reliability by 80%. Pass rate is 100% April through June. Dr. Huynh presented the pharmacy claim count from Q2 2017. In Medi-Cal, there were 549,455 approved claims and 229,922 denied claims. In	Dr. Liu and Dr. Huynh to verify computational methodology on prior authorization approval rate with other similar plans. Revise Goal column for next report.

	Healthy Kids, there were 1,086 approved claims and 1,557 denied claims. In CMC, there were 79,550 approved claims and 34,778 denied claims.	
	MTM Oversight (2017Q1 & 2017Q2) Dr. Otomo presented the Medication Therapy Management (MTM) Oversight update. Comprehensive medication review (CMR) completion rate was at 23% as of August; no data yet for September. On track for goal of 22% completion rate at year end.	
	Emergency Rx Access Monitoring Dr. Huynh presented the Emergency Prescription Access Report. Procedure will be updated. DHCS recommended being more proactive regarding prescriptions that were not received (one of the findings, other finding was around prior authorization language needing to be more "member friendly"). Asked for committee feedback on prior authorization letters. Should one be issued specific to provider and one letter specific to member? No preference from committee members.	
	Discussion and Recommendations for changes to SCFHP Cal MediConnect Formulary & Prior Authorization Criteria Dr. Huynh presented an overview of the MedImpact 2Q2017 P&T minutes as well as the MedImpact 3Q2017 P&T Part D Actions.	Upon motion duly made and seconded the MedImpact 2Q2017 P&T Minutes, and MedImpact 3Q2017 P&T Part D Actions were approved as submitted.
	Discussion and Recommendations for Changes to SCFHP Medi-Cal & Healthy Kids Formulary & Prior Authorization Criteria Formulary Modifications Dr. Otomo presented the formulary changes since the last P&T meeting. Notable changes included remove nystatin oral powder, Biltricide, Mistassist from formulary. Add generic fluticasone/salmeterol respiclick to formulary with QL 1/30 days. Change ST on Symbicort to look for 5/180 days of generic fluticasone/salmeterol. Add QL 10.2/30 days to Symbicort. Add Gilenya to formulary with PA and QL 1/day for PO option of MS treatment. Change QL on diltiazem 12 hr ER to 2/day. Change refill threshold on narcotic analgesics from 85% to 90% to prevent opioid overutilization. Add age limit for use in ≥ 12 years to all tramadol containing products. Recommendation by committee member Peter Nguyen that health plan notify all providers about formulary changes regarding top ten medications prescribed. Asked if committee would like formulary changes sent monthly or quarterly. Committee requested quarterly.	Upon motion duly made and seconded, formulary modifications were approved as presented.

Santa Clara
Family Health Plan

	Prior Authorization Criteria
	- Dr. Otomo presented the following PA criteria for approval by the committee:
	  - Reauthorization-Opioids
	  - Hepatitis C
	  - Tymlos (abaloparatide)
	  - Adapalene(Differin)
	  - Proventil HFA (albuterol sulfate)
	  - Calcipotriene (Dovonex)
	  - Darifenacin (Enablex)
	  - Glatopa (glatiramer acetate)
	  - Modafinil (Provigil)
	  - Nicotine inhaler/nasal spray (Nicotrol/Nicotrol NS)
	  - Lovaza (omega-3-Acid Ethyl Esters)
	  - Elmiron (pentosan polysulfate sodium)
	  - Lyrica (pregabalin)
	  - Testosterone gel (Androgel)
	  - Tetrabenazine (Xenazine)
		Upon motion duly made and seconded, prior authorization criteria were approved as requested.

	DHCS Medi-Cal CDL Updates & Comparability Dr. McCarty presented the DHCS Medi-Cal Updates and Comparability. For June 2017, five drugs added and one dosage form added. No proposed action for June 2017. For July 2017, one drug with quantity restriction added, two with strength added, and one with dosage form added. No proposed action for July 2017. For August 2017, one drug with prior authorization required added, two with dosage form added. No proposed action for August 2017.	Upon motion duly made and seconded, all recommendations were approved and presented.

	New Drugs and Class Reviews
	New Drug Reviews
	Dr. McCarty presented the following new drug reviews:
	  - Bevyxxa (betrixaban) –Extended duration VTE prophylaxis in acutely ill medical patients at high risk of VTE.
	  - COPD – Trelegy Ellipta-Remain non-formulary with trial of up to 2 preferred COPD inhaler(s).
	  - Tremfya (guselkumab) - New moderate-to-severe plaque psoriasis treatment.
	  - Hepatitis C – Vosevi and Mavyret, Add Mavyret to preferred for specific genotype w/ prior authorization guideline
	  - Glaucoma-Vuyzulta, Rhopressa, and Roclatan; CRL and FDA filing.
	  - ADHD-Proposed actions-Continue Focalin XR, Concerta, Metadate CD, and Strattera as formulary with added quantity limit of 1 per day. Metadate ER quantity limit
		Upon motion duly made and seconded, all recommendations were approved as presented.

	2/day. Remove step for Focalin XR. Remove age limit restriction in adults for Strattera.	
	Drug Utilization and Spend Review Dr. McCarty presented the Drug Utilization and Spend Review report. MediCal top drug categories by Plan Paid were Diabetes, Infectious Disease-Viral, Inflammatory Disease, and Asthma/COPD. Top drug categories by prescription count were Hypertension, Allergy, Diabetes, Vitamin D or mineral deficiency. Cal MediConnect top drug categories by Plan Paid were Diabetes, Asthma/COPD, Behavioral Health-other, and Infectious Disease-viral. Top drug categories by prescription count were Hypertension, Diabetes, Lipid Irregular, and Behavioral Health-other.	
	Reconvene in Open Session Committee reconvened to open session at 7:55 p.m.	
6	**Discussion Items**	
	Pharmacy Policies - PH11 340B Program Compliance policy was created to make sure Pharmacy Department will comply with all requirements and restrictions of the Public Health Service Act Section 340B pertaining to managed care organization (MCO) and the prohibition against duplicate discount/rebates under Medicaid pertaining. - PH14 Medications for Cancer Clinical Trial policy was created to define the process that provides prescription drug coverage to members diagnosed with cancer and accepted into a phase I, phase II, phase III or phase IV clinical trial for cancer with therapeutic intended endpoints and not exclusively defined to test toxicity.	Upon motion duly made and seconded, policies PH11 and PH14 were approved as presented.
	P&T Charter Dr. Liu reviewed the P&T Charter with the committee. No changes, informational only.	
	Generic Pipeline – Informational Only	
7	**Adjournment at 8:02 PM**	

Santa Clara
Family Health Plan

Informational Updates

- CMO Health Plan Updates
- Prescription Drug PA or ST Exception Request Form (Revised Form 61-211)
- Appeals & Grievances

Santa Clara
Family Health Plan
The Spirit of Care

To: Providers

From: Jeff Robertson, MD, Chief Medical Officer

Date: December 6, 2017

Subject: **Mandatory Revised Drug Prior Authorization Form**

Dear Providers:

Pursuant to California Senate Bill 282 and Assembly Bill 374, the Department of Managed Health Care and the Department of Insurance require the use of a standard **Prescription Drug Prior Authorization or Step Therapy Exception Request Form.** The form has been revised as of December, 2016.

Effective January 1, 2018, providers must use the revised Prescription Drug Prior Authorization or Step Therapy Exception Request Form 61-211 (12/2016) for **Medi-Cal** and **Healthy Kids** members.

The form may be found attached here and at www.scfhp.com under Provider Resources > Provider Forms & Resources (Authorization).

- All form fields must be completed and
- Forms should be submitted with supporting clinical information for review of prior authorization and step therapy exception requests.

Santa Clara Family Health Plan will continue to accept the old Prescription Drug Prior Authorization Form (08/13) through December 31, 2017. From January 1, 2018, the previous version of the Prescription Drug Authorization Request Form (08/13) will no longer be accepted.

If you have any questions, please email our Pharmacy department at pharmacy@scfhp.com.

Thank you in advance for your cooperation!

Santa Clara
Family Health Plan

Metric & Financial Updates

- **Membership**
- **Pharmacy Dashboard**
- **Drug Utilization & Spend**

Santa Clara Family Health Plan
SCFHP Pharmacy & Therapeutics
Committee 12.14.17

Membership

	2017-07	2017-08	2017-09	2017-10	2017-11	2017-12
AM	104	N/A	N/A	N/A	N/A	N/A
HK	2,633	2,618	2,243	2,288	2,321	2,447
MC	261,287	262,871	261,702	260,518	258,633	258,106
CMC	7,525	7,405	7,383	7,326	7,349	7,389
Grand Total	**271,549**	**272,894**	**271,328**	**270,132**	**268,303**	**267,942**

Pharmacy Dashboard

	GOAL (if applicable)	Jul	Aug	Sep	Oct	Nov
Medi-Cal						
PA volume		1569	1747	1512	1563	1504
Standard PAs						
# Standard PA requests		1396	1565	1371	1434	1341
# Approved PAs		683	800	759	800	730
# Denied PAs		373	403	305	342	331
PA approval rate		49%	51%	55%	70%	69%
# Standard PAs completed within 24 hours		1396	1564	1370	1432	1341
% Standard PAs completed within 24 hours	95%	100.0%	99.9%	99.9%	99.9%	100.0%
Expedited PAs						
# Expedited PA requests		173	182	141	129	163
# Approved PAs		89	109	87	79	101
# Denied PAs		34	32	22	23	30
PA approval rate		51%	60%	62%	77%	77%
# Expedited PAs completed within 24 hours		173	182	140	128	163
% Expedited PAs completed within 24 hours	95%	100%	100%	99%	99%	100%
Biannual Inter-Rater Reliability	80%	10/19/2017				

	GOAL (if applicable)	Jul	Aug	Sep	Oct	Nov
Cal MediConnect						
Total PA volume		99	95	145	116	113
Standard PAs						
# Standard PA requests		82	79	119	83	83
# Approved PAs		54	54	102	50	50
# Denied PAs		11	15	17	15	18
PA approval rate		66%	68%	86%	77%	74%
# Standard PAs completed within 72 hrs		82	79	119	83	83
% Standard PAs completed within 72 hrs	100%	100.0%	100.0%	100.0%	100.0%	100.0%
Expedited PAs						
# Expedited PA requests		17	16	12	33	30
# Approved PAs		13	9	7	18	15
# Denied PAs		3	4	5	7	7
PA approval rate		76%	56%	58%	72%	68%
# Expedited PAs completed within 24 hrs		17	16	12	33	30
% Expedited PAs completed within 24 hrs	100%	100.0%	100.0%	100.0%	100.0%	100.0%
PA audit sample size		20	20	20	20	20
PA audit pass		20	pending	pending	pending	pending
PA audit fail		0	pending	pending	pending	pending
PA pass rate	100%	100%	pending	pending	pending	pending
MTM Eligible Members (YTD)		8,787	8,861	8,965	9,076	pending
MTM Qualified Members (YTD)		1,662	1,717	1,767	1,813	pending
MTM CMR Completion (YTD)		374	376	377	394	pending
MTM CMR Completion Rate (YTD)	22% (at year end)	23%	22%	21%	22%	pending
MTM Quarterly Oversight			pending			
Total claims		47,241	49,315	46,061	49,887	46,484
Approved claims		25,633	26,865	25,251	27,222	25,671
Rejected/Reversed claims		21,608	22,450	20,810	22,665	20,813
Claim approval rate		54%	54%	55%	55%	55%
Transition fills		31	35	43	44	52
PDE rejection rate		0.25%	0.27%	0.27%	0.29%	0.26%
Denied claims - % reviewed	75%	39%	95%	99%	74%	96%
Formulary, PA, & ST posted on website by 1st of the month - Date		30-Jun	31-Jul	31-Aug	29-Sep	29-Oct
Formulary, PA, & ST posted on website by 1st of the month - Measure	100%	100%	100%	100%	100%	100%
Formulary upload to CMS		1-Jun	6-Jul	1-Aug	5-Sep	3-Oct

Previous Quarter Claim Count

Approved & Denied Claims – Q3 2017

Carrier HQ Code	Approved Claim Count	Denied Claim Count
SAC01	517,334	213,766
SAC02	805	1,276
SAC06	77,278	29,476
Summary	**595,417**	**244,518**

Approved & Denied Claims – Q2 2017

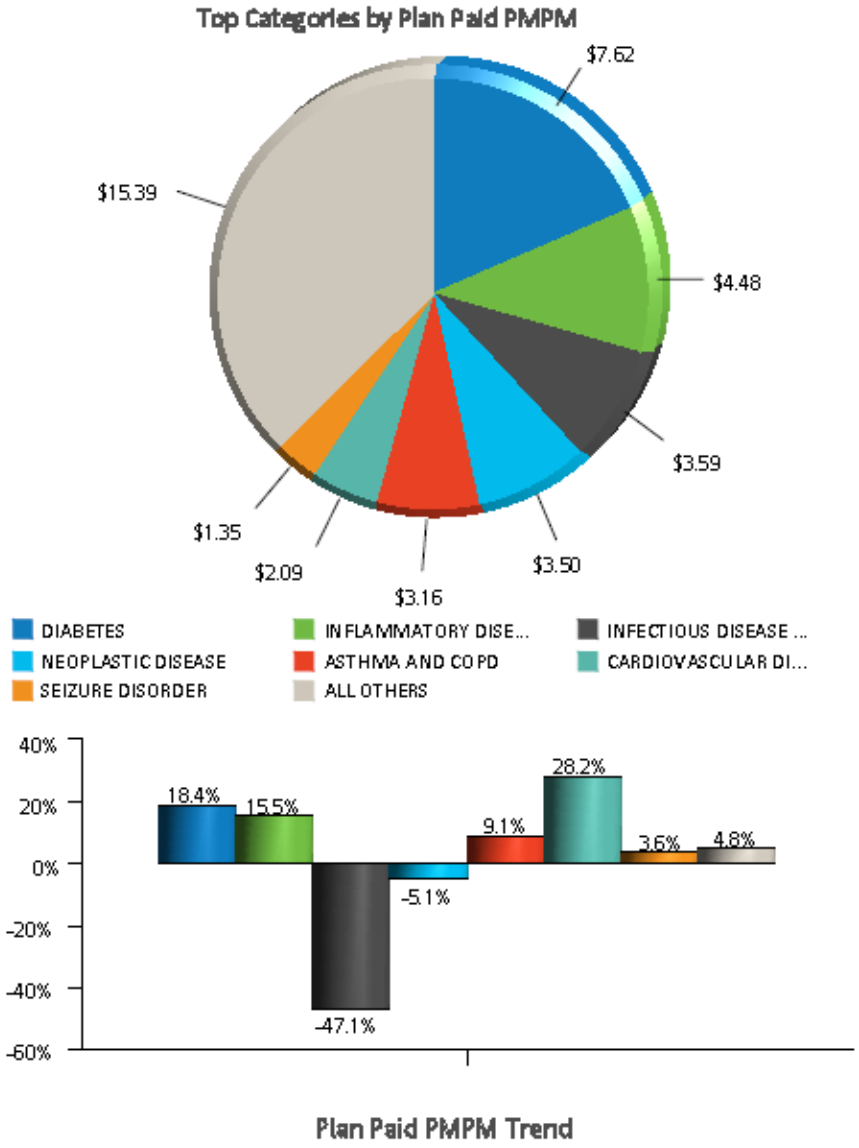
Carrier HQ Code	Approved Claim Count	Denied Claim Count
SAC01	549,455	229,922
SAC02	1,086	1,557
SAC06	79,550	34,778
Summary	**630,091**	**266,257**

Approved & Denied Claims – Q1 2017

Carrier HQ Code	Approved Claim Count	Denied Claim Count
SAC01	542,526	240,202
SAC02	953	1,458
SAC06	79,836	34,506
Summary	**623,315**	**276,166**

SAC Medi-Cal
Top Drug Categories

Report Period: 7/1/2017 to 9/30/2017
Comparison Period: 7/1/2016 to 9/30/2016
Benchmark: Medi-Cal



Top Drug Categories (GTC) by Plan Paid PMPM

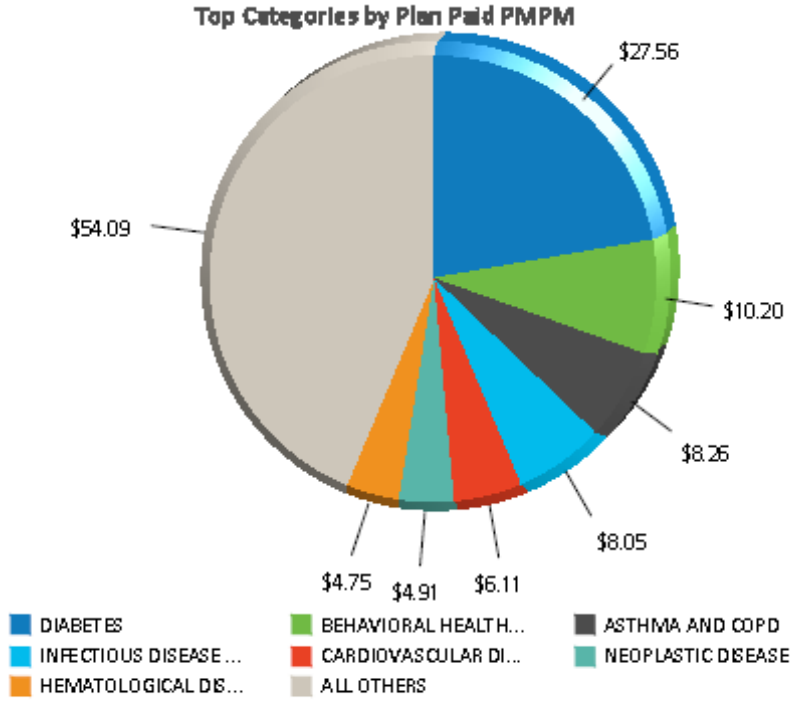
Rank	Prior Rank	Bench Rank	Drug Category	Utilizer Count	TC per DS	PMPM Change
1	2	1	DIABETES	10,088	$3.60	$1.19
2	3	4	INFLAMMATORY DISEASE	17,108	$8.14	$0.60
3	1	2	INFECTIOUS DISEASE - VIRAL	1,202	$69.53	($3.19)
4	4	5	NEOPLASTIC DISEASE	816	$43.47	($0.19)
5	5	3	ASTHMA AND COPD	8,563	$4.38	$0.26
6	6	6	CARDIOVASCULAR DISEASE - HYPERTENSION	20,469	$0.55	$0.46
7	7	7	SEIZURE DISORDER	7,571	$1.58	$0.05
			ALL OTHERS		$1.09	$0.70

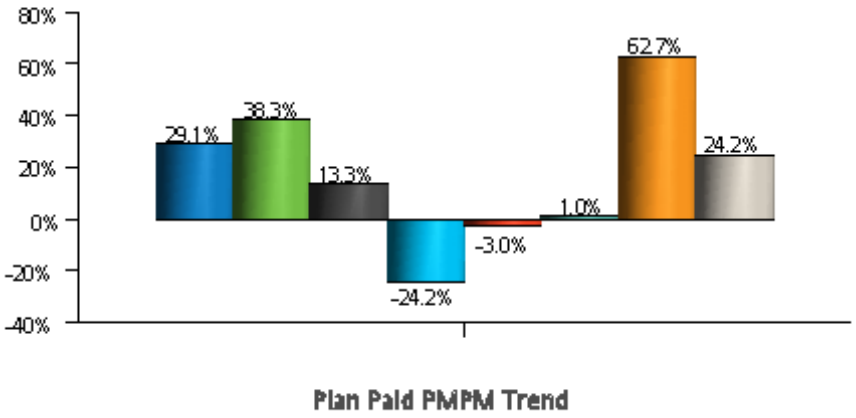
Top Drug Categories (GTC) by Rx Count

Rank	Prior Rank	Bench Rank	Drug Category	Utilizer Count	TC per DS	Rx Trend
1	1	1	CARDIOVASCULAR DISEASE - HYPERTENSION	20,469	$0.55	0.8%
2	2	2	DIABETES	10,088	$3.60	5.9%
3	3	9	VITAMIN AND/OR MINERAL DEFICIENCY	18,189	$0.12	2.2%
4	4	5	ALLERGY	19,181	$0.28	8.4%
5	6	11	CARDIOVASCULAR DISEASE - LIPID IRREGULAR	14,387	$0.27	5.1%
6	5	3	BEHAVIORAL HEALTH - ANTIDEPRESSANTS	9,553	$0.51	0.9%
7	8	4	INFLAMMATORY DISEASE	17,108	$8.14	2.5%
			ALL OTHERS		$2.62	2.0%

SAC Cal MediConnect
Top Drug Categories

Report Period: 7/1/2017 to 9/30/2017
Comparison Period: 7/1/2016 to 9/30/2016
Benchmark: MMP





Top Drug Categories (GTC) by Plan Paid PMPM

Rank	Prior Rank	Bench Rank	Drug Category	Utilizer Count	TC per DS	PMPM Change
1	1	1	DIABETES	2,191	$4.00	$6.20
2	3	7	BEHAVIORAL HEALTH - OTHER	1,134	$5.55	$2.83
3	4	2	ASTHMA AND COPD	884	$6.44	$0.97
4	2	3	INFECTIOUS DISEASE - VIRAL	191	$49.76	($2.57)
5	5	4	CARDIOVASCULAR DISEASE - HYPERTENSION	4,664	$0.49	($0.19)
6	6	14	NEOPLASTIC DISEASE	158	$48.14	$0.05
7	9	6	HEMATOLOGICAL DISORDERS	2,066	$1.39	$1.83
			ALL OTHERS		$1.63	$10.55

Top Drug Categories (GTC) by Rx Count

Rank	Prior Rank	Bench Rank	Drug Category	Utilizer Count	TC per DS	Rx Trend
1	1	1	CARDIOVASCULAR DISEASE - HYPERTENSION	4,664	$0.49	-7.1%
2	2	2	DIABETES	2,191	$4.00	-4.3%
3	3	4	CARDIOVASCULAR DISEASE - LIPID IRREGULAR	3,430	$0.36	-4.0%
4	4	13	BEHAVIORAL HEALTH - OTHER	1,134	$5.55	-7.6%
5	5	8	BEHAVIORAL HEALTH - ANTIDEPRESSANTS	1,418	$0.56	-10.2%
6	7	5	HEMATOLOGICAL DISORDERS	2,066	$1.39	-6.0%
7	6	9	SEIZURE DISORDER	1,337	$1.69	-7.4%
			ALL OTHERS		$3.49	-3.0%

Santa Clara
Family Health Plan

Cal MediConnect Formulary & Prior Authorization Criteria

- MedImpact 3Q2017 P&T Minutes
- MedImpact 4Q2017 P&T Part D Actions
- SCFHP Part B PA Grid

Santa Clara Family Health Plan
SCFHP Pharmacy & Therapeutics Committee 12.14.17

ANTIEMETICS (ASSOCIATED WITH CANCER CHEMOTHERAPY)	
Brand	**Generic**
Aloxi	Palonosetron
Emend	Aprepitant
Emend IV	Fosaprepitant

NEUROMUSCULAR BLOCKING AGENTS	
Brand	**Generic**
Botox	OnabotulinumtoxinA
Dysport	AbobotulinumtoxinA
Myobloc	RimabotulinumtoxinB
Xeomin	IncobotulinumtoxinA

ERYTHROPOIESIS STIMULATING AGENTS	
Brand	**Generic**
Aranesp	Darbepoetin alfa
Epogen, Procrit	Epoetin alfa

GAUCHER'S DISEASE	
Brand	**Generic**
Cerezyme	Imiglucerase
Elelyso	Taliglucerase
Vpriv	Velaglucerase

HEREDITARY ANGIOEDEMA	
Brand	**Generic**
Berinert, Cinryze	Compliment C1 esterase inhibitor
Kalbitor	Ecallantide

IV IMMUNOGLOBULIN (IVIG)	
Brand	**Generic**
Baygam, Flebogamma, Gamastan, Gammagard, Gammaplex, Gamunex, Gamunex-C, Hizentra, Octagam, Privigen, Vivaglobin	Immune globulin

MULTIPLE SCLEROSIS	
Brand	**Generic**
Tysabri	Natalizumab
Ocrevus	Ocrelizumab

OPHTHALMIC AGENTS	
Brand	**Generic**
Eylea	Aflibercept
Lucentis	Ranibizumab

OSTEOPOROSIS OR BONE MODIFIERS	
Brand	**Generic**
Aredia	Pamidronate

PULMONARY HYPERTENSION	
Brand	**Generic**
Flolan Veletri	Epoprostenol
Remodulin	Treprostinil

RHEUMATOLOGY/IMMUNOSUPPRESSANTS	
Brand	**Generic**
Actemra	Tocilizumab
Orencia	Abatacept
Remicade	Infliximab
Inflectra	Infliximab-dyyb
Stelara	Ustekinumab

RESPIRATORY	
Brand	**Generic**
Aralast, Aralast NP, Glassia, Prolastin, Prolastin C, Zemaira	α-1 proteinase inhibitor
Cinqair	Reslizumab
Nucala	Mepolizumab
Xolair	Omalizumab
Synagis	Palivizumab

MISCELLANEOUS	
Brand	**Generic**
Nplate	Romiplostim
Spinraza	Nusinersen

Santa Clara
Family Health Plan

Medi-Cal / Healthy Kids Formulary & Prior Authorization Criteria

- Formulary Modifications
- Prior Authorization Criteria
- SCFHP Medical Pharmacy PA Grid
- DHCS Medi-Cal CDL Updates & Comparability
- New Drugs and Class Reviews

Santa Clara Family Health Plan
SCFHP Pharmacy & Therapeutics Committee 12.14.17

2017 SCFHP Medi-Cal Formulary Changes

Formulary Change	Rationale	BCR Date	Effective Date	Approved
Change QL on alendronate 10mg to 1/day	align with dosing recommendations per package insert	10/17/2017	9/21/2017	J. Robertson
Add Mavyret to formulary with PA and QL 3/day	new hepatitis C drug; align with AASLD guideline recommendations	10/12/2017	9/21/2017	J. Robertson
Add glatiramer acetate 40mg/ml with PA and QL 12/28 days	new generic release; add another option for multiple sclerosis treatment; Glatopa 20mg/ml already on formulary	10/17/2017	10/11/2017	J. Robertson
Add vitamin D3 50,000 unit capsule to formulary	low cost generic	10/17/2017	10/12/2017	J. Robertson
Remove PA from dutasteride and add QL 1/day and ST to look for 5/180 days of finasteride 5mg.	formulary clean-up; align with dosing recommendations in package insert	10/27/2017	11/1/2017	J. Robertson
Add QL 1/day to finasteride 5mg	formulary clean-up; align with dosing recommendations in package insert	10/27/2017	11/1/2017	J. Robertson
Add ST to alogliptin/pioglitazone to look for 5/120 days of metformin plus another oral antihyperglycemic agent or GLP-1 agonist	formulary clean-up; align with ST for alogliptin and alogliptin/metformin	10/27/2017	6/15/2017	J. Robertson
Add Tears Again, Lubrifresh PM, and Tears Naturale PM ophthalmic ointment products to formulary	formulary clean-up	11/7/2017	11/1/2017	J. Robertson
Add estradiol 0.025mg/24h and 0.0375mg/24h transdermal patches to formulary with QL 8/28 days	formulary clean-up; align with dosing recommendations in package insert	11/7/2017	11/1/2017	J. Robertson
Add QL 8/28 days to estradiol biweekly transdermal patches. Add QL 4/28 days to estradiol weekly transdermal patches.	align with dosing recommendations in package insert	11/7/2017	11/1/2017	J. Robertson
Add Shingrix to formulary with AL ≥ 50 years old and QL 2/lifetime	align with CDC recommendations	11/7/2017	10/30/2017	J. Robertson
Add glatiramer acetate 20mg/ml with PA and QL 30/30 days	new generic release	11/7/2017	11/1/2017	J. Robertson

Formulary Change	Rationale	BCR Date	Effective Date	Approved
Remove Glatopa 20mg/ml from formulary	generic glatiramer acetate made available	11/7/2017	11/1/2017	J. Robertson
Update ST on methylphenidate ER (generic Concerta) to look for 5/365 days of both dextroamphetamine/amphetamine XR (generic Adderall XR) AND a formulary methylphenidate ER product OR dexmethylphenidate product	3Q17 P&T decision	11/7/2017	9/21/2017	J. Robertson
Add QL 1/day to methylphenidate ER (generic Concerta)	3Q17 P&T decision	11/7/2017	9/21/2017	J. Robertson
Remove ST from dexmethylphenidate ER (generic Focalin XR). Add missing strengths of dexmethylphenidate (25mg, 35mg, 40mg) to formulary. Add QL 1/day to dexmethylphenidate ER.	3Q17 P&T decision	11/7/2017	9/21/2017	J. Robertson
Add methylphenidate LA 60mg to formulary with DL 31 days (to align with other methylphenidate LA products). Add QL 1/day to methylphenidate LA.	3Q17 P&T decision	11/7/2017	9/21/2017	J. Robertson
Add QL 1/day to methylphenidate CD	3Q17 P&T decision	11/7/2017	9/21/2017	J. Robertson
Add QL 2/day to methylphenidate ER (generic Methylin ER)	3Q17 P&T decision	11/7/2017	9/21/2017	J. Robertson
Remove AL from atomoxetine	3Q17 P&T decision	11/7/2017	9/21/2017	J. Robertson
Add missing package size of Makena 250mg/ml (1 ml vial) to formulary with PA	formulary clean-up	11/7/2017	11/1/2017	J. Robertson
Change ST on Spiriva to look for 5/180 days of any of the following: Atrovent HFA, ipratropium inhalation solution, ipratropium/albuterol inhalation solution, Symbicort.	Spiriva ST previously included Dulera, but Dulera was removed from formulary	11/7/2017	11/1/2017	J. Robertson
Remove grandfathering from Lantus products	Basaglar Kwikpen contains same active ingredient and available on formulary without prior authorization	11/17/2017	12/1/2017	J. Robertson

Formulary Change	Rationale	BCR Date	Effective Date	Approved
Remove calcipotriene/betamethasone ointment from formulary	calcipotriene and betamethasone dipropionate available as separate agents on formulary	11/17/2017	11/1/2017	J. Robertson
Remove Vanatol solution from formulary	high cost agent; generic butalbital/APAP/ caffeine products available on formulary	11/17/2017	11/1/2017	J. Robertson
Remove Trianex ointment from formulary	high cost agent; generic triamcinolone ointment available on formulary	11/17/2017	11/1/2017	J. Robertson
Change sodium chloride 0.9% irrigation solution from Tier 3 to Tier 1	may be covered under the pharmacy benefit	11/22/2017	11/1/2017	J. Robertson
Add leucovorin 25mg tablet to formulary	*formulary clean-up*	*pending signature*	*12/15/2017*	*J. Robertson*
Remove Zepatier from formulary	*Mavyret and Epclusa are available on formulary and supported by AASLD guidelines*	*Pending Q4 P&T*		

Santa Clara Family Health Plan

hepatitis C
HEP C

TREATMENT CRITERIA FOR THE MANAGEMENT OF CHRONIC HEPATITIS C

Treatment Criteria

1. Treatment considerations and choice of regimen for hepatitis C virus infected patients:
   A. Please refer to AASLD guidelines (hcvguidelines.org) or package insert for recommended treatment regimens and durations.

Treatment Naïve		
Genotype 1a	Without cirrhosis ~~OR with compensated cirrhosis~~	Mavyret (glecaprevir/pibrentasvir) for 8 weeks ~~Zepatier (elbasvir/grazoprevir) for 12 weeks~~ ~~*Requires that there is no predicted resistance to elbasvir on NS5A resistance testing~~ ~~Mavyret (glecaprevir/pibrentasvir) for 8 or 12 weeks~~
	With compensated cirrhosis	Mavyret (glecaprevir/pibrentasvir) for 12 weeks
Genotype 1b	Without cirrhosis ~~OR with compensated cirrhosis~~	Mavyret (glecaprevir/pibrentasvir) for 8 weeks ~~Zepatier (elbasvir/grazoprevir) for 12 weeks~~ ~~Mavyret (glecaprevir/pibrentasvir) for 8 or 12 weeks~~
	With compensated cirrhosis	Mavyret (glecaprevir/pibrentasvir) for 12 weeks
Genotype 2	Without cirrhosis ~~OR with compensated cirrhosis~~	Primary Mavyret (glecaprevir/pibrentasvir) for 8 ~~or 12~~ weeks Secondary Epclusa (sofosbuvir/velpatasvir) for 12 weeks
	With compensated cirrhosis	Primary Mavyret (glecaprevir/pibrentasvir) for 12 weeks Secondary Epclusa (sofosbuvir/velpatasvir) for 12 weeks

Genotype 3	Without cirrhosis	Primary Mavyret (glecaprevir/pibrentasvir) for 8 weeks Secondary Epclusa (sofosbuvir/velpatasvir) for 12 weeks

	With compensated cirrhosis	Primary Mavyret (glecaprevir/pibrentasvir) for 12 weeks Secondary Epclusa (sofosbuvir/velpatasvir) for 12 weeks *~~RAV~~ RAS testing for Y93H polymorphism is recommended for cirrhotic pts. If present, add RBV to regimen.
Genotype 4	Without cirrhosis ~~OR with compensated cirrhosis~~	Mavyret (glecaprevir/pibrentasvir) for 8 weeks ~~Zepatier (elbasvir/grazoprevir) for 12 weeks~~ ~~Mavyret (glecaprevir/pibrentasvir) for 8 or 12 weeks~~
	With compensated cirrhosis	Mavyret (glecaprevir/pibrentasvir) for 12 weeks
Genotype 5 or 6	Without cirrhosis~~With and without cirrhosis~~	Primary Mavyret (glecaprevir/pibrentasvir) for 8 ~~or 12 weeks~~weeks Secondary Epclusa (sofosbuvir/velpatasvir) for 12 weeks
	With compensated cirrhosis	Primary Mavyret (glecaprevir/pibrentasvir) for 12 weeks Secondary Epclusa (sofosbuvir/velpatasvir) for 12 weeks

Treatment Naïve		
~~Genotype 1,2,3, or 4~~All genotypes	Decompensated cirrhosis	Epclusa (sofosbuvir/velpatasvir) and RBV for 12 weeks *Epclusa (sofosbuvir/velpatasvir) for 24 weeks (*RBV ineligible*)

Formatted Table

Formatted: Underline

Formatted: Font: Italic

2. Treatment candidates:
   A. Evidence of Stage 2 or greater hepatic fibrosis/cirrhosis including one of the following:
      i. Liver biopsy confirming a METAVIR score F2 or greater; OR
      ii. Transient elastography (Fibroscan®) ≥ 7.5 kPa; OR
      iii. FibroSure® ≥ 0.48; OR
      iv. APRI > 0.7 OR
      v. FIB-4 > 3.25
      vi. Shear Wave Elastography (SWE) ≥ 7.1 kPa (1.54 m/s) OR SWE measurement showing Stage 2 fibrosis or greater per lab specific fibrosis staging
   B. Evidence of extra-hepatic manifestation of hepatitis C virus, such as
      i. type 2 or 3 essential mixed cryoglobulinemia with end- organ manifestations (e.g. vasculitis), or

ii. kidney disease (e.g. proteinuria, nephrotic syndrome or membranoproliferative glomerulonephritis)

C. Persons with hepatocellular carcinoma with a life expectancy of greater than 12 months
D. Pre- and post-liver transplant, or other solid organ transplant
E. HIV-1 co-infection
F. Hepatitis B co-infection
G. Other coexistent liver disease (e.g. nonalcoholic steatohepatitis)
H. Type 2 diabetes mellitus (insulin resistant)
I. Porphyria cutanea tarda
J. Debilitating fatigue impacting quality of life (e.g., secondary to extra-hepatic manifestations and/or liver disease)
K. Men who have sex with men with high-risk sexual practices
L. Active injection drug users
M. Persons on long-term hemodialysis
N. Women of childbearing age who wish to get pregnant
O. HCV-infected health care workers who perform exposure-prone procedures

3. Age requirements: Treatment candidate must be 18 years of age or older.
4. Other considerations
   A. Quantity Limits:
      i. Prescription of hepatitis C therapy will be dispensed in quantities up to 28 days at a time.
   B. Criteria for Reauthorization/Continuation of Therapy:
      i. Initial authorization criteria have been met, and
      ii. Evidence of lack of adherence may result in denial of treatment reauthorization.
      iii. Missed medical appointments related to the hepatitis C virus may result in denial of treatment authorization.
   C. Laboratory Testing:
      i. Laboratory testing should be consistent with current AASLD/IDSA guidelines
         1. Within 12 weeks of starting therapy:
            a. CBC with differential; INR
            b. Hepatic function panel (albumin, total and direct bilirubin, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase levels)
            c. GFR
            d. TSH if IFN is used
         2. Any time prior to starting therapy:
            a. HCV genotype and subtype
            b. Quantitative HCV RNA
   D. Populations Unlikely to Benefit from Hepatitis C Virus Treatment: According to AASLD/IDSA hepatitis C virus Guidelines, “patients with limited life expectancy for whom hepatitis C virus therapy would not improve symptoms or prognosis do not require treatment. Chronic hepatitis C is associated with a wide range of comorbid conditions. Little evidence exists to support initiation of hepatitis C virus treatment in patients with limited life expectancy (less than 12 months) due to non–liver-related comorbid conditions. For these patients, the benefits of hepatitis C virus treatment are unlikely to be realized, and palliative care strategies should take precedence.” In patients with a life expectancy less than 12 months, treatment is not recommended.

E. Retreatment: Retreatment will be considered where there is evidence that such retreatment will improve patient outcomes. Please refer to AASLD guidelines for recommended retreatment regimens (hcvguidelines.org).

Retreatment in prior failed PEG-IFN plus RBV		
Genotype 1a	Without cirrhosis ~~OR with compensated cirrhosis~~	Mavyret (glecaprevir/pibrentasvir) for 8 weeks ~~Zepatier (elbasvir/grazoprevir) for 12 weeks~~ ~~*Requires that there is no predicted resistance to elbasvir on NS5A resistance testing~~
	With compensated cirrhosis	Mavyret (glecaprevir/pibrentasvir) for 12 weeks
Genotype 1b	Without cirrhosis ~~Without cirrhosis OR with compensated cirrhosis~~	Mavyret (glecaprevir/pibrentasvir) for 8 weeks ~~Zepatier (elbasvir/grazoprevir) for 12 weeks~~
	With compensated cirrhosis	Mavyret (glecaprevir/pibrentasvir) for 12 weeks
Genotype 2	Without cirrhosis ~~Without cirrhosis OR with compensated cirrhosis~~	Primary Mavyret (glecaprevir/pibrentasvir) for 8 weeks Secondary Epclusa (sofosbuvir/velpatasvir) for 12 weeks ~~Epclusa (sofosbuvir/velpatasvir) for 12 weeks~~
	With compensated cirrhosis	Primary Mavyret (glecaprevir/pibrentasvir) for 12 weeks Secondary Epclusa (sofosbuvir/velpatasvir) for 12 weeks
Genotype 3	Without cirrhosis	~~Epclusa (sofosbuvir/velpatasvir) for 12 weeks~~ ~~*RAV testing for Y93H polymorphism is recommended. If present, add RBV to regimen.~~Epclusa (sofosbuvir/velpatasvir) for 12 weeks *RAS testing for Y93H polymorphism is recommended. If present, add RBV to regimen.
	With compensated cirrhosis	~~Epclusa (sofosbuvir/velpatasvir) and RBV for 12 weeks~~Vosevi (sofosbuvir/velpatasvir/voxilaprevir) for 12 weeks
Genotype 4	Without cirrhosis ~~Without cirrhosis OR with compensated cirrhosis~~	Mavyret (glecaprevir/pibrentasvir) for 8 weeks ~~Zepatier (elbasvir/grazoprevir) for 12 weeks~~ ~~*If had prior on-treatment virologic failure (failure to suppress or breakthrough) on PEG-IFN/RBV, extend to 16 weeks and add RBV~~
	With compensated cirrhosis	Mavyret (glecaprevir/pibrentasvir) for 12 weeks
Genotype 5 or 6	Without cirrhosis ~~Regardless of cirrhosis status~~	~~Epclusa (sofosbuvir/velpatasvir) for 12 weeks~~Primary Mavyret (glecaprevir/pibrentasvir) for 8 weeks Secondary Epclusa (sofosbuvir/velpatasvir) for 12 weeks
	With compensated cirrhosis	Primary Mavyret (glecaprevir/pibrentasvir) for 12 weeks

Commented [TO1]: Pg 126 of PDF guidelines. Mavyret x16w is listed as 'ALTERNATIVE' regimen; Epclusa is the only 'RECOMMENDED' regimen here.

Formatted: Not Highlight

Commented [TO2]: Pg 129 of PDF guidelines. Mavyret x16w is listed as 'ALTERNATIVE' regimen. Vosevi x12w OR Zepatier+Sovaldi x12w are listed as 'RECOMMENDED' regimens here.

Formatted: Not Highlight

Formatted: Not Highlight

Formatted: Not Highlight

		Secondary Epclusa (sofosbuvir/velpatasvir) for 12 weeks

Retreatment in prior failed non-NS5A inhibitor, sofosbuvir-containing regimen		
Genotype 1 (regardless of subtype)	Without cirrhosis OR with compensated cirrhosis	Mavyret (glecaprevir/pibrentasvir) for 12 weeks

Retreatment in prior failed ~~Sovaldi (sofosbuvir)~~sofosbuvir plus RBV ~~with or without PEG-IFN~~		
Genotype 2	Without cirrhosis OR with compensated cirrhosis~~Regardless of cirrhosis status~~	Primary Mavyret (glecaprevir/pibrentasvir) for 12 weeks Secondary Epclusa (sofosbuvir/velpatasvir) for 12 weeks ~~Epclusa (sofosbuvir/velpatasvir) and RBV for 12 weeks~~
~~Genotype 3~~	~~Regardless of cirrhosis status~~	~~Epclusa (sofosbuvir/velpatasvir) and RBV for 12 weeks~~
~~Genotype 4~~	~~With decompensated cirrhosis~~	~~Epclusa (sofosbuvir/velpatasvir) and RBV for 24 weeks~~

Retreatment in prior failed HCV NS3 protease inhibitor (Victrelis (boceprevir), Incivek (telaprevir), Olysio (simeprevir)) plus PEG-IFN and RBV		
Genotype 1 (regardless of subtype)	Without cirrhosis OR with compensated cirrhosis ~~Without cirrhosis OR with compensated cirrhosis~~	Primary Mavyret (glecaprevir/pibrentasvir) for 12 weeks ~~(IIa, B)~~ Secondary Epclusa (sofosbuvir/velpatasvir) for 12 weeks ~~Mavyret (glecaprevir/pibrentasvir) for 12 weeks (IIa, B)~~ ~~Zepatier (elbasvir/grazoprevir) and RBV for 12 weeks (ALTERNATIVE regimen; IIa, B)~~ ~~*For *genotype 1a*, if have baseline high fold-change NS5A RASVs for elbasvir, extend to 16 weeks~~

~~**Retreatment in prior failed Olysio (simeprevir) and Sovaldi (sofosbuvir)**~~		
~~Genotype 1 (regardless of subtype)~~	~~Without cirrhosis~~	~~Deferral of treatment is recommended, pending availability of data, for patients who do not have cirrhosis and do not have reasons for urgent retreatment~~
	~~With compensated cirrhosis~~	~~Testing for RAVs that confer decreased susceptibility to NS3 protease inhibitors and to NS5A inhibitors is recommended to guide retreatment regimen~~
	~~When using nucleotide-based (e.g. sofosbuvir) dual DAA therapy, a treatment duration of 24 weeks is recommended, and RBV (unless contraindicated) should be added~~	

Formatted: Normal, Indent: Left: 0"
Formatted: Not Highlight
Formatted: Not Highlight
Formatted: Not Highlight
Formatted: Font: (Default) Arial, 10 pt
Formatted: Normal, Indent: Left: 0"
Formatted: Not Highlight
Formatted: Not Highlight
Formatted: Font color: Red, Not Highlight
Formatted: Not Highlight
Formatted: Not Highlight
Formatted: Font: 10 pt
Formatted: Normal
Formatted Table
Formatted: Font color: Red
Formatted: Font color: Red
Formatted: Font: (Default) Arial, 10 pt
Formatted: Normal, Indent: Left: 0"
Formatted: Font: (Default) Arial, 10 pt
Formatted: Normal, Indent: Left: 0"

Retreatment in prior failed NS5A inhibitor (Harvoni, Daklinza, Zepatier, Technivie, Viekira Pak)		
Genotype 1 (regardless of subtype)	Without cirrhosis	Deferral of treatment is recommended, pending availability of data, for patients who do not have cirrhosis and do not have reasons for urgent retreatment
	With compensated cirrhosis	Testing for RAVs that confer decreased susceptibility to NS3 protease inhibitors and to NS5A inhibitors is recommended to guide retreatment regimen
	With decompensated cirrhosis	Epclusa (sofosbuvir/velpatasvir) and RBV for 24 weeks
	When using nucleotide-based (e.g. sofosbuvir) dual DAA therapy, a treatment duration of 24 weeks is recommended, and RBV (unless contraindicated) should be added	
	If available, nucleotide-based (e.g. sofosbuvir) triple or quadruple DAA regimens may be considered. In these settings, treatment duration ranges from 12 to 24 weeks and RBV (unless contraindicated) is recommended	
Genotype 4	With decompensated cirrhosis	Epclusa (sofosbuvir/velpatasvir) and RBV for 24 weeks

Retreatment in prior failed NS5A inhibitor DAA (Harvoni, Daklinza, Zepatier, Technivie, Viekira Pak, Epclusa, Mavyret)		
Genotype 1 (regardless of subtype)	Without cirrhosis OR with compensated cirrhosis	Mavyret (glecaprevir/pibrentasvir) for 16 weeks (IIa, B) Vosevi (sofosbuvir/velpatasvir/voxilaprevir) for 12 weeks
		Vosevi (sofosbuvir/velpatasvir/voxilaprevir) for 12 weeks (I, A) 89k Mavyret (glecaprevir/pibrentasvir) for 16 weeks (IIa, B) 63k

Retreatment in prior failed DAA (including NS5A inhibitors)		
Genotype 3	Regardless of cirrhosis status	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) for 12 weeks *If prior failed DAA was NS5A inhibitor and cirrhosis, add RBV
Genotype 3*, 4, 5, or 6	Without cirrhosis OR with compensated cirrhosis	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) for 12 weeks
		*Genotype 3: If prior failed DAA was NS5A inhibitor and cirrhosis, add RBV

Retreatment in prior failed sofosbuvir- or NS5A-based treatment		
All genotypes	Decompensated cirrhosis	Epclusa (sofosbuvir/velpatasvir) and RBV for 24 weeks

F. Treatment Failure

Formatted: Font color: Red

Commented [TO3]: Pg 116 of PDF guidelines. Mavyret is listed as 'ALTERNATIVE' regimen; Vosevi is the only 'RECOMMENDED' regimen here.

Formatted: Not Highlight

Formatted: Font color: Auto, Not Highlight

Formatted: Not Highlight

Formatted: Font color: Auto, Not Highlight

Formatted: Not Highlight

Formatted: Not Highlight

Formatted: Underline, Not Highlight

Formatted: Not Highlight

Formatted: Not Highlight

Formatted: Not Highlight

Formatted: Not Highlight

Formatted: Not Highlight

Formatted: Underline

i. If HCV viral load is detectable at week 4 of treatment, repeat HCV RNA viral load testing is recommended after 2 additional weeks of treatment (treatment week 6). If HCV viral load has increased by greater than 10-fold (>1 log10 IU/mL) on repeat testing at week 6 (or thereafter), then discontinuation of HCV treatment is recommended.
ii. The significance of a positive HCV RNA at week 4 that remains positive, but lower, at week 6 or week 8 is unknown. No recommendation to stop therapy or extend therapy can be provided at this time.

G. Criteria for coverage of Investigational Services (Title 22 § 51303)
   i. Investigational services are not covered except when it is clearly documented that all of the following apply:
      1. Conventional therapy will not adequately treat the intended patient's condition;
      2. Conventional therapy will not prevent progressive disability or premature death;
      3. The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service;
      4. The investigational service is the lowest cost item or service that meets the patient's medical needs and is less costly than all conventional alternatives;
      5. The service is not being performed as a part of a research study protocol;
      6. There is a reasonable expectation that the investigational service will significantly prolong the intended patient's life or will maintain or restore a range of physical and social function suited to activities of daily living;
      7. All investigational services require prior authorization. Payment will not be authorized for investigational services that do not meet the above criteria or for associated inpatient care when a beneficiary needs to be in the hospital primarily because she/he is receiving such non-approved investigational services.

H. Unlabeled use of medication: Authorization for unlabeled use of drugs shall not be granted unless the requested unlabeled use represents reasonable and current prescribing practices. The determination of reasonable and current prescribing practices shall be based on:
   i. Reference to current medical literature.
   ii. Consultation with provider organizations, academic and professional specialists.

For Internal Use Only :

Effective: 07/21/2015 DHCS

Version	Date	P&T	Comments/Changes
1	07/21/2015	3Q2015	TO: Created
2	03/22/2016	1Q2016	TO: AASLD updated guidelines to include Zepatier
3	07/27/2016	3Q2016	DH: AASLD updated guidelines to include Epclusa
4	09/06/2017	9/21/2017	TO: Added shear wave elastography (SWE) as an accepted fibrosis scoring system per DHCS guidance; P&T Approved 3Q2017.
5	10/10/2017	Pending 4Q2017	DH/TO: Add Mavyret to criteria~~, length of therapy based on package insert.~~ based on 9/21/17 AASLD updated guidelines~~.~~

Ciclopirox 8% sol

PENLAC
CICLODAN

Santa Clara Family Health Plan

DRUG PRIOR AUTHORIZATION REQUEST CRITERIA

Generic	Brand	HICL	GPID	ROUTE
CICLOPIROX 8%	**PENLAC CICLODAN**	**16915**	**8040**	**TOPICAL**

Prior Authorization Required

Authorization Criteria:

1. Diagnosis of onychomycosis or tinea unguium of fingernail(s) or toenail(s); **and**
2. Failure, clinically significant adverse effect(s), or contraindication(s) to oral terbinafine; **and**
3. Patient is 12 years of age or older; **and**
4. Dose does not exceed 6.6mL per month

Approval period:

- Approve by **GPID** for 6 months.

Reauthorization Criteria:

1. Updated clinical chart notes; **and**
2. Total duration of treatment does not exceed 12 months.

Reauthorization Approval period:

- Approve by **GPID** for 6 months.

For Internal Use Only

Rationale for clinical intent:

- Ensure appropriate utilization of ciclopirox 8% solution based on FDA approved indications.

FDA Approved Indications:

- For the topical treatment of onychomycosis of the fingernails and toenails due to *Trichophyton rubrum.* Every 7 days after ciclopirox is removed with alcohol, file away (with emery board) loose nail material and trim nails, as required or as directed by a healthcare professional.[Ref]

References:

- Acella Pharmaceuticals, LLC. Enablex package insert. Alpharetta, GA. Revised 04/2013.

ANTIEMETICS (ASSOCIATED WITH CANCER CHEMOTHERAPY)	
Brand	**Generic**
Aloxi	Palonosetron
Emend	Aprepitant
Emend IV	Fosaprepitant

NEUROMUSCULAR BLOCKING AGENTS	
Brand	**Generic**
Botox	OnabotulinumtoxinA
Dysport	AbobotulinumtoxinA
Myobloc	RimabotulinumtoxinB
Xeomin	IncobotulinumtoxinA

ERYTHROPOIESIS STIMULATING AGENTS	
Brand	**Generic**
Aranesp	Darbepoetin alfa
Epogen, Procrit	Epoetin alfa

GAUCHER'S DISEASE	
Brand	**Generic**
Cerezyme	Imiglucerase
Elelyso	Taliglucerase
Vpriv	Velaglucerase

HEREDITARY ANGIOEDEMA	
Brand	**Generic**
Berinert, Cinryze	Compliment C1 esterase inhibitor
Kalbitor	Ecallantide

IV IMMUNOGLOBULIN (IVIG)	
Brand	**Generic**
Baygam, Flebogamma, Gamastan, Gammagard, Gammaplex, Gamunex, Gamunex-C, Hizentra, Octagam, Privigen, Vivaglobin	Immune globulin
Prolia; Xgeva	Denosumab
Reclast, Zometa	Zoledronic acid

MULTIPLE SCLEROSIS	
Brand	**Generic**
Tysabri	Natalizumab
Ocrevus	Ocrelizumab

OPHTHALMIC AGENTS	
Brand	**Generic**
Eylea	Aflibercept
Lucentis	Ranibizumab

OSTEOPOROSIS OR BONE MODIFIERS	
Brand	**Generic**
Aredia	Pamidronate

PULMONARY HYPERTENSION	
Brand	**Generic**
Flolan Veletri	Epoprostenol
Remodulin	Treprostinil

RHEUMATOLOGY/IMMUNOSUPPRESSANTS	
Brand	**Generic**
Actemra	Tocilizumab
Orencia	Abatacept
Remicade	Infliximab
Inflectra	Infliximab-dyyb
Stelara	Ustekinumab

RESPIRATORY	
Brand	**Generic**
Aralast, Aralast NP, Glassia, Prolastin, Prolastin C, Zemaira	α-1 proteinase inhibitor
Cinqair	Reslizumab
Nucala	Mepolizumab
Xolair	Omalizumab
Synagis	Palivizumab

MISCELLANEOUS	
Brand	**Generic**
Nplate	Romiplostim
Spinraza	Nusinersen

SAC Medi-Cal Updates

Date	Drug	Summary of Change to FFS CDL	SAC Formulary Status	Proposed Action
09/17	FLUTICASONE FUROATE (nasal)	Drug Added	Non-Form	No Action
09/17	FLUTICASONE PROPIONATE (nasal)	Drug Added	Formulary with QL	No Action
09/17	OLAPARIB	Strength/Dosage Form (tabs) Added	Non-Form	No Action
10/17	INFLUENZA VIRUS VACCINE	Strength Removed	Formulary	No Action
11/17	PROMETHAZINE W/ PHENYLEPHRINE & CODEINE	Quantity Limited, Fills Limited	Formulary	Add QL, Match CDL

Shingrix

- **Approved:** October 20, 2017
- **Indication**: For prevention of herpes zoster (“shingles”) in adults aged 50 years and older
- **Mechanism of action:** recombinant herpes zoster subunit vaccine; induces immune responses, including cell-mediated CD4+ T-cell responses
- **Dosing:** 2 doses (0.5 mL each) given IM at (1) Month 0 and (2) Months 2-6
- **Clinical Summary**
  - Shingrix is a non-live alternative to Zostavax
  - When indirectly compared to Zostavax, Shingrix has substantially improved overall efficacy, improved persistency of efficacy, and improved efficacy in older populations

Shingrix: Proposed Actions

Drug	Proposed Action

Shingrix	• Add to formulary
	  • Add age limit to allow in 50 and older
	  • Add quantity limit of 2 doses per lifetime

Zostavax	• Remove from formulary

Cardiovascular Disease Outcomes

Drug class	Drug	CV clinical trial	Composite MACE Outcomes	FDA approved CV indication
SGLT-2i	**Jardiance** (empagliflozin)	EMPA-REG OUTCOME	**Positive**	√
	Invokana (canagliflozin)	CANVAS	**Positive**	Submitted sNDA 10/2017
	Farxiga (dapagliflozin)	DECLARE-TIMI 58	TBD (2019)	
	Ertugliflozin *(under review)*	VERTIS CV	TBD (2019)	
GLP-1 RA	**Ozempic** (semaglutide)	SUSTAIN 6	**Positive**	TBD
	Victoza (liraglutide)	LEADER	**Positive**	√
	Trulicity (dulaglutide)	REWIND	TBD (2019)	
	Tanzeum (albiglutide)	HARMONY	TBD (2019)	
	Bydureon (exenatide microspheres)	EXCSEL	**Neutral**	
	Adlyxin (lixisenatide)	ELIXA	**Neutral**	
	ITCA 650 (cont. exenatide) *(under review)*	FREEDOM – CVO	**Neutral**	
DPP-4i	**Januvia** (sitagliptin)	TECOS	**Neutral**	
	Tradjenta (linagliptin)	CARMELINA and CAROLINA	TBD (1Q 2018)	
	Nesina (alogliptin)	EXAMINE	**Neutral**	
	Onglyza (saxagliptin)	SAVOR TIMI-53	**Neutral**	

Diabetes: Proposed Actions

Drug	Proposed Action
GLP-1 Receptor Agonists	• Tanzeum – No change • Ozempic – Decision pending launch

SGLT-2 Inhibitors	• Invokana/Invokamet – No change
	• Jardiance/Synjardy/Synjardy XR – Add to formulary
	  • Add step therapy (required trial of Metformin + oral/GLP-1RA)
	  • Add quantity limit
	  • Jardiance & Synjardy XR =1/day
	  • Synjardy = 2/day

DPP-4 Inhibitors	• Januvia/Janumet/Janumet XR – Remove from formulary • Alogliptin/Alogliptin combinations – No change (now preferred DPP4i)

Chimeric Antigen Receptor (CAR) T-Cell Therapies

	Kymriah (tisagenlecleucel)	Yescarta (axicabtagene ciloleucel)
Approval Date	8/30/17	10/18/17
Indication	Pediatric (≤ 25yrs) R/R B-cell ALL[1]	Adult R/R large B-cell lymphoma[2] (Not indicated for PCNSL)
Mechanism of Action	Anti-CD19 CAR T-cell autologous therapy	
Dosing	One-time IV infusion	One-time IV infusion
Manufacturer	Novartis	Kite Pharma/Gilead

R/R = Relapsed or refractory; PCNSL = Primary central nervous system lymphoma

[1]Indicated for treatment of patients ≤ 25 years of age with B-cell precursor acute lymphoblastic leukemia that is refractory or in 2nd or later relapse.

[2]Indicated for treatment of adult patients with R/R large B-cell lymphoma after ≥2 lines of systemic therapy, including diffuse large B-cell lymphoma not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.