CIGNA MEDICARE ADVANTAGE: PATHWAY TO ENHANCE COMPLIANCE WITH STATIN USE

Together, all the way.®

Cigna®

Statin therapy and STARS

Why is statin use a Healthcare Effectiveness Data and Information Set (HEDIS®) *and* Part D STARS measure?

For every 10,000,000 (NNT) Medicare beneficiaries at high risk receiving effective high intensity statin therapy:

Prevention of the following:*

- 42,918 cardiovascular deaths
- 81,300 myocardial infarctions
- 138,888 composite cardiovascular outcomes

NNT = number needed to treat

*Statins for Prevention of Cardiovascular Disease in Adults: Evidence Report and Systematic Review for the US Preventive Services Task Force. Agency for Healthcare Research and Quality, Chou R, Dana T, Blazina I, Daeges M, Jeanne TL JAMA, 316(19):2008-2024, 31 Oct 2016. Cited by: 75 articles | PMID: 27838722

Statin quality measures in STARs

Statin Use in Patients with Diabetes (SUPD)

Eligible: Patients, ages 40-75, with two fills of diabetic medication

Compliant: Eligible patients with at least one fill of a statin medication (any intensity) during the measurement year

Exclusions:

ICD-10* coding for any of the following:

- Liver disease including hepatitis, alcoholic liver disease, toxic liver disease, hepatic failure, hepatic fibrosis/sclerosis, cirrhosis**
- Polycystic ovary syndrome (PCOS)
- Prediabetes, abnormal blood glucose
- Pregnancy and lactation
- Rhabdomyolysis, myopathy, myositis, adverse effect of anti-hyperlipidemic drugs
- End-stage renal disease (ESRD)
- Hospice

Statin Use in Patients with Cardiovascular Disease (SPC)

Eligible: Male patients, ages 21-75, and female patients, ages 40-75, with clinical atherosclerotic cardiovascular disease (ASCVD)

Compliant: Patients dispensed at least one high-intensity or moderate-intensity statin during measurement year

Exclusions:

ICD-10 coding for any of the following:

- Pregnancy
- End-stage renal disease (ESRD)
- Cirrhosis
- Myalgia, myositis, myopathy, or rhabdomyolysis
- Patients who had in vitro fertilization, or have taken clomiphene in the measurement year or year prior
- Patients 66 and older with frailty and advanced illness

*International Classification of Diseases, Tenth Revision
**Proposed change to cirrhosis only in 2022

Frequently asked questions about statin prescribing

Q: Is there an algorithm to help manage muscle pain in patients taking statins?
Yes. The American College of Cardiology/American Heart Association (ACC/AHA) developed an algorithm for evaluating statin intolerance and safely reintroducing therapy (tools.acc.org/StatinIntolerance).

Q: What are other considerations for managing statin intolerances?
- Intolerance to one or more statins does not indicate intolerance to all statins.
- In addition to non-statin causes, onset of muscle symptoms in a patient who has previously tolerated statins can be caused by changes in their clinical status. Continue to consider secondary causes.
- Consider characteristics of each statin, such as metabolism, lipophilicity, and drug interactions when prescribing.

Q: What alternative dosing regimens exist for statin use, and when should I use them?
- It is preferable to use daily dosing of statins since they have been studied and proven to reduce clinical events.
- Alternate-day dosing may improve the tolerability of statins in patients experiencing myalgia, and can reasonably be tried in patients unable to tolerate daily statin therapy.
- Small studies have evaluated every-other-day dosing of atorvastatin, fluvastatin (40 mg), and rosuvastatin once weekly.
- Results suggest that to achieve similar LDL cholesterol lowering, the every-other-day dose needs to be on average twice that of the daily dose.
- As a best practice, consider re-prescribing with a new prescription that notes the new dosage to avoid patient confusion about the correct regimen.

Q: Do statins cause myopathy?
The ACC estimates that 10 to 20 patients in 10,000 are at risk for having muscle pain and weakness per year, which occurs symmetrically and proximally. When a patient does experience significant muscle toxicity with creatine kinase (CK) enzyme elevation, statin therapy should be discontinued. Once the patient's symptoms have resolved and CK level has returned to normal, the ACC recommends its Statin Intolerance Tool (tools.acc.org/StatinIntolerance) for management of statin intolerance.

Frequently asked questions about statin prescribing (continued)

Q: What statin medications does Cigna Medicare Advantage cover?

High-Intensity Statin Therapy	Moderate-Intensity Statin Therapy	Low-Intensity Statin Therapy
Daily dose lowers LDL-C by >50%, on avg.	*Daily dose lowers LDL-C by 30%-50%, on avg.*	*Daily dose lowers LDL-C by <30%, on avg.*
TIER 1: Atorvastatin 40 mg - 80 mg Rosuvastatin 20 mg - 40 mg	**TIER 1:** Atorvastatin 10 mg - 20 mg Simvastatin 20 mg - 40 mg Pravastatin 40 mg - 80 mg Rosuvastatin 5 mg - 10 mg Lovastatin 40 mg **TIER 3:** Livalo 2 mg - 4 mg	**TIER 1:** Simvastatin 10 mg Pravastatin 10 mg - 20 mg Lovastatin 20 mg **TIER 3:** Livalo 1 mg

Q: What if a patient shows intolerance, but not contraindication, to a statin medication?

Consider options such as:

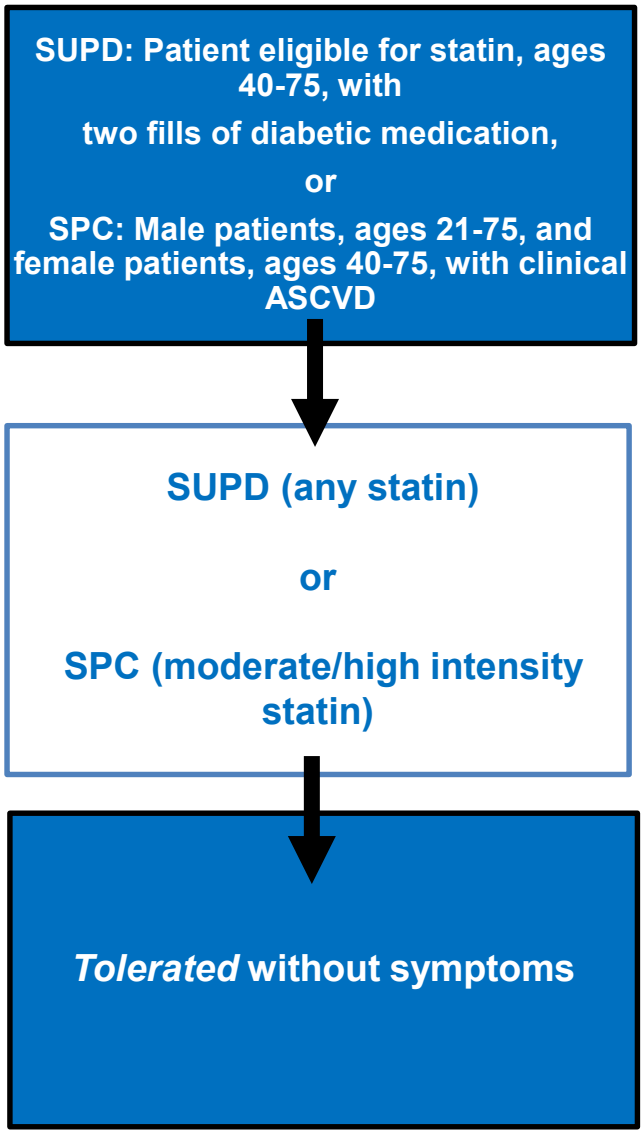
- a different statin medication
- alternate-day dosing
- a coenzyme (CoQ10) supplement
- increased water intake

For detailed steps, use the ACC Statin Intolerance tool at tools.acc.org/StatinIntolerance.

Q: Do statins dose need to be titrated?

Preferably, start on the lowest dose and titrate up. If a patient complains of muscle discomfort, immediately monitor serum creatine kinase and if raised repeat after three days' rest. If still raised, then consider changing to a lower dose or another statin, but not simvastatin.

Tolerance and intolerance of statin medication initiation



Most **patients tolerate statin therapy well.**

< 5%

+ symptoms (see slide 8)

> 95%

Most common adverse effects of statins (3% to 5% of patients)

- **Musculoskeletal:*** autoimmune necrotizing myopathy, statin-associated (rare), compartment syndrome of lower leg, disorder of muscle, rhabdomyolysis, myopathy, myositis, muscle cramps, rupture of tendon, asthenia
- **Gastrointestinal:** abdominal pain, constipation, nausea, flatulence, dyspepsia
- **Neurologic:** headache
- **Respiratory:** upper respiratory infection, epistaxis, dyspnea, interstitial pulmonary disease
- **Hepatic:** cholestatic hepatitis, increased liver enzymes, jaundice, liver failure
- **Dermatologic**: skin rash, pruritus, urticaria
- **Endocrine and metabolic**: Increased gamma-glutamyl transferase
- **Otic**: tinnitus
- **Genitourinary**: cystitis (interstitial)

*Enhanced susceptibility to statin-associated myopathy occurs in patients with hypothyroidism, acute or chronic renal failure, and obstructive liver disease.

Assessing the likelihood that the statin is causing the symptom

+ Symptoms on statin

***Stop statin**

***Check:**
Renal function, liver function, creatine kinase (CK), vitamin D, and thyroid stimulating hormones

CK ≥ 10 times upper limit of normal (ULN)

CK < 10 times ULN

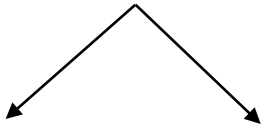
***See next slide**

Exclusions	SUPD	SPC
ESRD	Yes	Yes
Cirrhosis	Yes	Yes
Rhabdomyolysis	Yes	Yes
Myopathy	Yes	Yes
Liver Disease	Yes	Yes*

***Monitor and manage symptoms back to baseline.**
***Evaluate the probability of statin induced musculoskeletal (MSK) symptoms (see slide 10).**
***Document the statin intolerance (see table).**

Reintroduction of statin in patient with initial symptoms (CK < 10 times ULN)

Stop statin, treat hypothyroidism and vitamin D deficiency if present, and manage musculoskeletal symptoms through resolution.



If high intensity statin is required:

- Consider every other day dosing with titration to desired LDL-C level
  - **Atorvastatin 10-20 mg**
  - **Rosuvastatin 5-10 mg**
- Consider addition of coenzyme Q10 (CoQ10) 30-250 mg/day to prevent myopathy
- Encourage fluid intake

Note:

- Rosuvastatin can be used in severe renal impairment and has less drug to drug interactions.
- **Prescriptions should reflect specific dosing recommendations. For example, rosuvastatin #45 alternate dose for 90 days, rosuvastatin #12 weekly dose for 90 days.**

If low or moderate intensity statin is required:

- Consider every other day dosing with titration to desired LDL-C level
  - **Fluvastatin 40 mg**
- Consider daily dosing with titration to desired LDL-C level
  - **Pravastatin 10 mg**
  - **Fluvastatin 20 mg**
- Consider addition of coenzyme Q10 (CoQ10) 30-250 mg/day to prevent myopathy
- Encourage fluid intake

Note:

- Pravastatin can be used in severe liver impairment and has less drug to drug interactions.
- Fluvastatin can be used in severe renal impairment and has less drug to drug interactions.
- **Prescriptions should reflect specific dosing recommendations. For example, fluavstatin #45 alternate dose for 90 days.**

Evaluating the probability of statin-induced musculoskeletal symptoms

Parameter	Points
Distribution	
Symmetric hip or thigh aches	3
Symmetric calf or upper arm aches	2
Nonspecific, asymmetric or intermittent	1
Transient during statin use	0
Timing of symptom onset	
≥ 2 days but < 4 weeks	3
4-12 weeks	2
> 12 weeks	1
< 2 days	0
Dechallenge	
Improves upon withdrawal in 2 days to < 2 weeks	2
Improves upon withdrawal in 2-4 weeks	1
Does not improve upon withdrawal in > 4 weeks	0
Asymptomatic after 1 day	0
Rechallenge	
Same symptoms recur in ≥ 2 days but < 4 weeks	3
Same symptoms recur in 4-12 weeks	1
Response to nonstatin lipid lowering therapy	
Same symptoms as with statin occur with nonstatin drug	-5

Probability of statin induced muscle symptoms	Points
Probable	≥ 9
Possible	7-8
Unlikely	< 7

Mancini GB, Baker S, Bergeron J, et al. Diagnosis, prevention and management of statin adverse effects and intolerance: Canadian Consensus Working Group update. *Can J Cardiol* 2016;32:S35-65.

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References

1. Prevention and management of statin adverse effects: A practical approach for pharmacists – CPJ/RPC (Canadian Pharmacists Journal)

2. Statin muscle-related adverse events - UpToDate®