The Clinical and Financial Impact of Modifying Saxenda® (liraglutide) Utilization Management

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BACKGROUND

- The Network Health Plan (NHP) is an employer self-funded commercial health insurance plan sponsored by University of North Carolina (UNC) Health. Since its approval in 2015, Saxenda® (liraglutide) has been covered by the NHP pharmacy benefit, contributing to steadily rising plan spend as the second most expensive medication for the plan. The rate of plan paid drug cost has increased by approximately $25,000 per quarter, and plan spend was projected to increase at this rate through 2021.
- As a weight loss medication, Saxenda® is approved for chronic weight management in adults adjunctive to a reduced-calorie diet and increased physical activity. The 2016 AACE/ACE obesity guidelines recommend that weight-loss pharmacotherapy should only be used in adjunct to lifestyle modifications (reduced-calorie diet, physical activity programs and behavioral interventions).[1]
- To contain drug spend and ensure appropriate utilization, additional criteria was added to the Saxenda® coverage policy. Along with requiring members to seek care through a bariatric specialist, the edited policy required documentation of physical activity, dietary intervention, and smoking status. The new Saxenda® coverage policy became effective January 1, 2019.

PURPOSE

To assess the clinical and financial impact of modifying the Saxenda® coverage policy

METHODS

- Retrospective, single-center study approved by the Institutional Review Board at the University of North Carolina Medical Center
- All NHP patients with a submitted prior authorization (PA) request for Saxenda® between January 1, 2018 and December 31, 2019 were reviewed.
- Data was collected for patients receiving initial approval through the historical policy, revised policy, and those receiving Saxenda® denials in 2019.
- Patients were identified using claims data on file and Saxenda® PA information housed in pharmacy benefit manager software.
- Patients were included if they met the following criteria:
  - Age ≥ 18 years at time of PA request
- Patients were excluded if they met the following criteria:
  - Concomitantly receiving another weight loss therapy while on Saxenda®
  - No documentation of baseline or follow-up weights
- **Primary outcome**:
  - Weight loss from baseline in patients receiving Saxenda® therapy under each coverage policy (historical vs. revised)
- **Secondary outcomes**:
  - Weight changes in patients that were denied Saxenda® coverage through the revised policy
  - Cost savings realized after the Saxenda® coverage policy was revised
- Data was extracted to allow for one-year pre and post intervention analysis using student t-test (GraphPad QuickCalcs).[3]

Disclosures: Authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation.

RESULTS

Table 1: Patient Baseline Characteristics

Saxenda® Approvals	Historical Policy CY2018 N = 51	Revised Policy CY2019 N = 17
Female sex, n (%)	46 (90.2)	16 (94.1)
Mean age, years [SD]	46 ± 8.5	47 ± 9.7
Mean baseline body-mass index (kg/m^2)	38.8	39.5
Adherent (achieved PDC ≥ 0.80), n (%)	17 (33.3)	11 (64.7)
Weight-related comorbidities, n (%) Type 2 diabetes mellitus Hypertension Atherosclerotic cardiovascular disease Hyperlipidemia	 6 (11.8) 15 (29.4) 1 (2) 13 (25.5)	 1 (5.9) 9 (52.9) 0 (0) 4 (23.5)
Life-style modifications, n (%): Physical activity Dietician Diet program Non-smoker	 ---	 15 (88.2) 15 (88.2) 2 (11.8) 17 (100)
CY2019 Saxenda® Denials	**Converted N = 7**	**No Conversion N = 43**
Female sex, n (%)	5 (71.4)	40 (93.0)
Mean age, years [SD]	44 ± 8.8	45 ± 9.6
Mean baseline body-mass index (kg/m^2)	39.0	39.7
Adherent (achieved PDC ≥ 0.80), n (%)	1 (14.3)	---
Weight-related comorbidities, n (%) Type 2 diabetes mellitus Hypertension Atherosclerotic cardiovascular disease Hyperlipidemia	 0 (0) 2 (28.6) 0 (0) 2 (28.6)	 11 (25.6) 20 (46.5) 3 (7) 9 (20.9)
Life-style modifications, n (%): Physical activity Dietician Diet program Non-smoker	 6 (85.7) 4 (57.1) 2 (28.6) 7 (100)	 39 (90.7) 14 (32.6) 22 (51.2) 43 (100)
Previously received Saxenda, n (%)	2 (28.6)	14 (32.6)

PDC = proportion of days covered

Table 2: Weight Loss from Baseline for Saxenda® Approvals

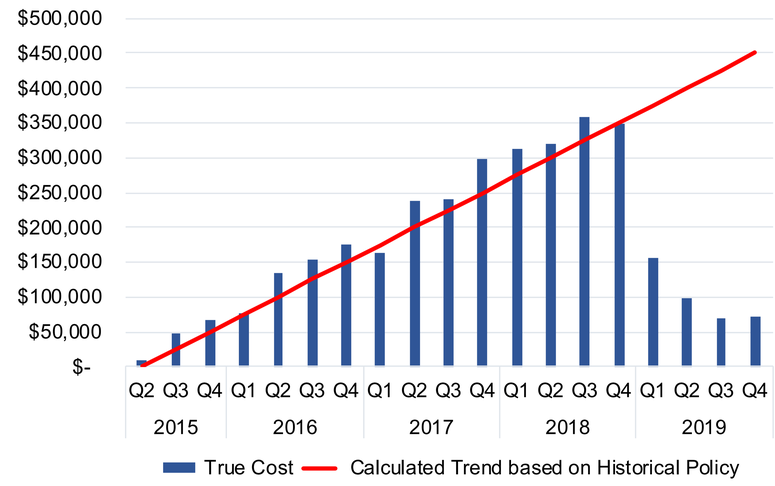
	Historical Policy CY2018	Revised Policy CY2019
Mean baseline weight (kg)	106.25	104.87
Mean follow-up weight (kg)	101.28	100.26
Mean weight loss (kg) (%)	**4.97 (4.68)**	**4.61 (4.40)**
95% CI; p-value	**3.03 – 3.75; p = 0.8332**	
Mean time from baseline* (weeks)	20.6	19.7

*Accepted range was 16-28 weeks. Upper limit was 28 weeks, which encompassed the 16-week drug trial in addition to a 12 week wash-out period before weight gain was expected to return.[2]

Table 3: Weight Loss for CY2019 Saxenda® Denials

	Converted	No Conversion
Mean baseline weight (kg)	110.28	110.90
Mean follow-up weight (kg)	109.06	110.95
Mean weight loss (kg) (%)	**1.21 (1.10)**	**-0.05 (0.05)**
95% CI; p-value	**-2.95 – 5.49; p = 0.5488**	
Mean time from baseline (weeks)	16.1	19.8

Figure 1. Plan Paid Cost of Saxenda® Utilization



Revising the Saxenda® policy disrupted the rising plan spend rate and resulted in a **$1.2 million** reduction in the CY2019 plan paid expense.

CONCLUSIONS

- There was no statistical difference in clinical response to Saxenda® therapy between the historical and revised coverage policies.
- Patients who were denied Saxenda® coverage through the revised policy did not experience significant weight gain.
- Switching to an alternative weight-loss agent did not result in greater weight loss compared to no therapy.
- Modifying Saxenda® utilization management was found to be cost-effective. The updated coverage policy resulted in a 3.2% reduction in total plan paid expense while only impacting 1% of members.
- Given lackluster weight loss results and lack of cardiovascular outcomes data, these results have informed the recommendation to remove Saxenda® from coverage under the NHP pharmacy benefit.
- Limitations of this study include:
  - Small sample size with a lack of external control group
  - Retrospective design
  - Variable follow-up time for collecting weight loss information

References:
1. AACE and ACE Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. *Endocr Pract.* 2016;22(Suppl 3).
2. le Roux CW, Astrup A, Fujioka K, et al. 3 years of liraglutide versus placebo for type 2 diabetes risk reduction and weight management in individuals with prediabetes: a randomised, double-blind trial. *Lancet.* 2017;389(10077):1399-1409.
3. GraphPad QuickCalcs. https://www.graphpad.com/quickcalcs/ttest1.cfm