

10/17/19

STATEMENT OF MEDICAL NECESSITY
AND PRESCRIPTION ORDERTANDEM
DIABETES CARE

"Confidential Patient Health Information"

This form serves as a prescription and Statement of Medical Necessity for the Tandem Insulin Pump and all related diabetes supplies to be provided by Tandem Diabetes Care or authorized distributors and/or product development partners.

| | | | |
|---|--|---|--|
| 1 | | PATIENT ORDER INFORMATION (CHECK ITEM BEING PRESCRIBED) | |
| PATIENT NAME (FIRST MIDDLE LAST) Sarah E Ford | | PATIENT STREET ADDRESS 1990 County Route 11 | |
| NEW INSULIN PUMP | | PUMP SUPPLIES | |
| <input checked="" type="checkbox"/> Insulin X2™ insulin pump with access to Basal-IQ™ technology <input type="checkbox"/> Insulin X2™ insulin pump with access to Control-IQ™ technology | | <input checked="" type="checkbox"/> Infusion Sets and Cartridges CARTRIDGE CHANGE FREQUENCY <input checked="" type="checkbox"/> Every 2 days (Qty. 50) <input type="checkbox"/> Every 2.25 days (Qty. 40) <input type="checkbox"/> Every 3 days (Qty. 30) | |
| ORDER INJECTION DATE (MM/DD/YYYY) 01/07/2020 | | INFUSION SET PREP <input checked="" type="checkbox"/> Skin Prep Wipes <input checked="" type="checkbox"/> Skin Transparent Dressing | |
| PRESCRIPTION DURATION Lifetime | | COGM SUPPLIES <input checked="" type="checkbox"/> Sensors - 365/365 <input checked="" type="checkbox"/> Transmitter - 4/365 <input checked="" type="checkbox"/> Receiver - 1/365 | |
| DIRECTIONS FOR USE: Site changes per manufacturer recommendation, up to 80 days unless otherwise noted. | | INFUSION SET FREQUENCY <input checked="" type="checkbox"/> Every 1 day (Qty. 90) <input checked="" type="checkbox"/> Every 2 days (Qty. 50) <input type="checkbox"/> Every 2.25 days (Qty. 40) <input type="checkbox"/> Every 3 days (Qty. 30) | |

| | | | |
|--|--|---|--|
| 2 | | CURRENT DIABETES THERAPY: <input type="checkbox"/> Insulin Pump (Use Current Settings) <input checked="" type="checkbox"/> Multiple Daily Injections | |
| (Pump start orders required for insulin start/saline training ok if clinic protocol) | | | |

| | | | |
|---|--|---------------------------------|--|
| DATE OF DIAGNOSIS (MM/YYYY) 01/01/2004 | | LATEST HBA1C - RESULT 7.90 % | |
| IDC-10 DIAGNOSIS CODE E10.65 | | DATE (MM/DD/YYYY) 10/17/2019 | |
| FOLLOW UP HBA1C - RESULT % | | DATE (MM/DD/YYYY) % | |

| | | | |
|---|--|---|--|
| <input checked="" type="checkbox"/> Patient/Caregiver has the ability to operate and can use an insulin pump to manage blood glucose <input type="checkbox"/> Current pump is out of warranty and/or its functionality no longer meets the patient's medical need (see "Other conditions" for details) | | <input checked="" type="checkbox"/> Variations in the day-to-day schedule and/or exercise prevent the achievement of successful glycemic control with multiple daily injections <input checked="" type="checkbox"/> Blood glucose logs indicate blood glucose is checked as required | |
| <input checked="" type="checkbox"/> Patient performs multiple daily injections consisting of 3-4 or more injections per day and is able to self-adjust insulin doses <input checked="" type="checkbox"/> Diabetes management reminders required (BG, meal bolus, infusion site change) | | <input type="checkbox"/> History of ER/hospital visits: diabetic ketoacidosis (DKA), severe hypoglycemia, other: | |
| <input checked="" type="checkbox"/> Despite frequent therapy adjustments, the patient experiences suboptimal glycemic control—evidenced by wide glycemic fluctuations ranging from 43 to 398 mg/dL | | | |

| | | | |
|--|--|--|--|
| <input type="checkbox"/> Patient is pregnant or planning pregnancy <input checked="" type="checkbox"/> Hypoglycemia unawareness | | <input type="checkbox"/> Nocturnal hypoglycemia | |
| <input checked="" type="checkbox"/> Dawn phenomenon (AM hyperglycemia) | | <input type="checkbox"/> Gastroparesis | |
| <input type="checkbox"/> Extreme insulin sensitivity | | <input type="checkbox"/> Hearing acuity requirement | |
| <input type="checkbox"/> Extreme insulin resistance | | <input type="checkbox"/> Infusion site disconnect required | |

| | | | |
|---|--|---|--|
| 3 | | STATEMENT OF MEDICAL NECESSITY FOR INSULIN PUMP USE (CHECK ALL THAT APPLY) | |
| PRESCRIBING PROVIDER NAME Rashant NADKARNI | | NPI 1346782695 186/MS5750 | |

| | | | |
|--|--|---|--|
| 3 | | PRESCRIBING PROVIDER NAME Rashant NADKARNI | |
| OFFICE STREET ADDRESS 3229 E Genesee St | | PHONE NUMBER +1(315)464-5726 | |
| CITY Syracuse | | FAX NUMBER +1(315)464-2510 | |
| STATE NY | | ZIP CODE 13214-2016 | |
| PRACTICE NAME AND NOTES Jaslin Diabetes Center Syracuse | | EMAIL ADDRESS | |

I certify that I am the prescribing provider identified above and have reviewed all of the order information above. Any statement on my letterhead attached hereto, has been reviewed and signed by me. I certify that all the medical necessary information is true, accurate, and complete, to the best of my knowledge. The patient's record contains supporting documentation, which substantiates the utilization and medical necessity of the products named above. I understand the indications for use and associated warnings and precautions of the Tandem Diabetes Care® products I have prescribed herein. I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability. A copy of this order will be retained as part of the patient's medical record.

| | | | |
|---------------------------------|--|--|--|
| X | | PRESCRIBING PROVIDER SIGNATURE (SIGNATURE STAMPS ARE NOT ACCEPTABLE) | |
| DATE (MM/DD/YYYY) 11/13/2020 | | | |

JOSLIN ADULT CENTER
PROVIDER-BASED
3229 E Genesee Street
SYRACUSE NY 13214-2061
Visit date: 10/17/2019
Ford, Sarah E
MRN: 1093909, DOB: 6/16/1991, Sex: F

Progress Notes by Prashant Nadkarni V, MD at 10/17/2019 10:00 AM

Author: Prashant Nadkarni V, MD Service: —
Filed: 10/17/2019 11:40 AM
Encounter Date: 10/17/2019
Editor: Prashant Nadkarni V, MD (Physician)
Author Type: Physician
Status: Signed

Subjective:

Subjective Patient ID: Sarah E Ford is a 28 y.o. female here for follow up of type 1 diabetes diagnosed in March 2004 and hypothyroidism diagnosed in January 2008. She was accompanied to the visit by her boyfriend.

HPI

LOV : 12/9/2015

Patient used to see Eric Rodriguez, PA-C @ Crouse - Last visit July 2019

Pt had ER visits at Crouse for DKA Jan 2018. Patient also works As School bus driver

| Component | Hemoglobin A1C | Latest Ref Rng | 4.0 - 6.0 % |
|------------|----------------|----------------|-------------|
| 6/15/2010 | 8.1 (H) | | |
| 9/21/2010 | 9.1 (H) | | |
| 12/27/2010 | 8.4 (H) | | |
| 3/28/2011 | 7.6 (H) | | |
| 6/27/2011 | 8.1 (H) | | |
| 9/26/2011 | 7.6 (H) | | |
| 12/27/2011 | 8.4 (H) | | |
| 3/29/2012 | 8.5 (H) | | |
| 7/3/2012 | 8.8 (H) | | |
| 10/4/2012 | 8.2 (H) | | |
| 1/15/2013 | 8.4 (H) | | |
| 5/7/2013 | 9.0 (H) | | |

| Component | Hemoglobin A1C | Latest Ref Rng & Units | 4.0 - 6.0 % |
|-----------|----------------|------------------------|-------------|
| 6/4/2013 | 9.6 (H) | | |
| 8/20/2013 | 10.1 (H) | | |
| 9/23/2013 | 9.8 (H) | | |
| 12/4/2013 | 10.6 (H) | | |
| 1/21/2014 | 11.0 (H) | | |
| 3/24/2014 | 9.7 (H) | | |
| 4/28/2014 | | | |
| 6/2/2014 | 12.9 (H) | | |
| 8/6/2014 | 10.8 (H) | | |
| 2/2/2015 | 10.5 (H) | | |
| 4/3/2015 | | | |

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Progress Notes by Prashant Nadkarni V, MD at 10/17/2019 10:00 AM (continued)

| | |
|-----------|----------|
| 5/7/2015 | 11.4 (H) |
| 8/10/2015 | 10.8 (H) |
| 12/9/2015 | 10.7 (H) |

4/30/2019
a1c:8.4

| | |
|------------------------|----------------|
| Component | Hemoglobin A1C |
| Latest Ref Rng & Units | 4.0 - 6.0 % |
| 10/17/2019 | 7.9 (H) |

DIABETES: Novolog flex pen with meals 12-20 units meal (about 45 units/day) with Toujeo 45 units q 9 PM.

In past, Patient has used Animas Insulin pump since 2/2014 - stopped in 2016,

Basal: 1.4 u/hr

Bolus:

I:C-

00:00-1:6

10:30 1:6

17:00-1:6

target:

00:00-120-140

6:00-110-130

21:00-120-140

ISF:

00:00-1:30

Target: 110-130

Per pump down load, pt hardly using boluses.

(Lantus 16 units qAM And 18 units HS and Novolog flex pen (per algorithm below).-usually 6-12 units/meal (about 100 units/day).

In past pt also used to follow:

Target 120, ISF 40, 1 unit for 3 gm carbs (usually 12-15 units /meal)

Patient used to use Animas ping meter - for 2 yrs -requested break in 8/2012.

Pt works at Tops -after finishing highschool.

She has started Exercise-walking-pt walks 1/2 hr 2 days of week.

SMBG: pt was using Freestyle libre - last use 4 month due to cost issues.

Now uses onetouch ultra 4.1/d

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Ave 234, range 67- 426
Wide glycemc variation

pt used to see dr. Mooney , psychiatrist For anxiety - Pt on Zolof with good result- No suicidal thoughts .

She is Not having many episodes of low glucose..-has awareness. No LOC.

She had not needed glucagon since her last visit. Her urine was checked for ketones when her blood sugars were over 250 mg/dL, and ketones had been negative.

She was having annual eye exams Last 2/2019 (vision works , Oswego)

No Feet complaints .
She Wears diabetes identification tag and had gotten a tattoo placed on her lower leg.
Feet numbness +, feet care d/w pt .

Renal :

| | | |
|------------------------|-------------------|-----------|
| Component | Latest Ref Rng | 8/20/2013 |
| Microlbumin/creatinine | <20.0 ug/mg creat | 10.8 |

| | | |
|------------------------|-------------------|-----------|
| Component | Latest Ref Rng | 1/21/2014 |
| Microlbumin/creatinine | <20.0 ug/mg creat | 30.1 (H) |

6/9/2015
S. Creat 0.7 .

Renal
4/30/2019

s. creat :0.7
Urine MAC: 40

Sarah's blood sugars were being checked 1-2 times a day with a OneTouch meter. Wide excursions- mostly high .
Hypoglycemic episodes mostly related to Novolog use .

GOP0A0- LMP- 9/13/2019

-pt used to spot- hence OCP was changed - t/u by Gyn at Oswego. .

ADDITIONAL HISTORY:

Patient's medications, allergies, past medical, surgical, social and family histories were reviewed and updated as appropriate.

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REVIEW OF SYSTEMS:

Review of Systems

Constitutional: Negative for appetite change.

HENT: Negative for hearing loss and dental problem.

Eyes: Negative for visual disturbance (**Feels pressure in the eyes**).

Respiratory: Negative for cough and shortness of breath.

Gastrointestinal: Negative for abdominal pain.

Bowel movements regular

Genitourinary: Negative for dysuria.

Musculoskeletal: Negative for myalgias and arthralgias.

Skin: Negative for pallor.

Neurological: Positive for headaches (**When high**).

Psychiatric/Behavioral: Negative for suicidal ideas, self-injury and dysphoric mood.

Objective:

Objective

Visit Vitals

BP

110/68 (BP Location: Right arm,

Patient Position: Sitting, Cuff

size: Adult Large)

60

Pulse

12

Resp

1.735 m (5' 8.31")

Ht

91.6 kg (202 lb)

Wt

30.44 kg/m²

BMI

Physical Exam

Vitals reviewed.

Constitutional: She is oriented to person, place, and time. She appears well-developed.

She has No tremor of her outstretched arms

HENT:

Head: Normocephalic.

Mouth/Throat: No oropharyngeal exudate.

Eyes: No scleral icterus.

No exophthalmos

Neck: Normal range of motion. Neck supple. No Thyromegaly present.

Palpable thyroid gland - no nodules

Cardiovascular:

S1, S2 normal

Pulmonary/Chest: Effort normal and breath sounds normal. No respiratory distress.

Abdominal: Soft. She exhibits no mass. There is no tenderness.

Musculoskeletal: Normal range of motion.

Neurological: She is alert and oriented to person, place, and time.

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Skin: Skin is warm. No rash noted.
Psychiatric: She has a normal mood and affect. Her behavior is normal. Judgment and thought content normal.

LABORATORY:

Office Visit on 10/17/2019

| Component | Date | Value | Ref Range | Status |
|-------------------------|------------|-------|----------------|--------|
| • POC Glucose | 10/17/2019 | 301* | 70 - 140 mg/dL | Final |
| • Hemoglobin A1c | 10/17/2019 | 7.9* | 4.0 - 6.0 % | Final |
| • Estimated Avg Glucose | 10/17/2019 | 180* | <126 mg/dL | Final |

Assessment:
Assessment

and
Plan:
Plan

1. T1DM:since 2004 (age 12) - uncontrolled- A1c is improving but still has significant glycemic variability. ..
With nephropathy -

As per SMBG and recent Hba1c, pts diabetes control appears to be inadequate/poor. Importance of good control of DM and it's implications on microvascular complications d/w pt. Questions answered. DCCT/UKPDS data reviewed with patient.
Importance of diet/exercise d/w pt. Will refer to DM ed /Dietician . Glycemic And Hba1c targets d/w pt. Hypoglycemia management d/w pt . Sick day management d/w pt. Therapeutic options including insulin Pump therapy d/w pt (pt used to be on insulin pump till 8/2012-preferred insulin injections). Risk/benefits/indications /side-effects of each d/w pt-questions answered .

Pt has erratic SMBG with wide glycemic excursions .
Barrier: Social stress/possible depression-

Pt agrees to check SMBG more consistently and follow the scale and send us log of the glucose /insulin readings .

To ct Lisinopril 2.5 mg -pregnancy contraindication d/w pt and accompanying boyfriend -pt should stop lisinopril when planning for pregnancy or first indication of pregnancy.
diabetic nephropathy.
I would recommend following measures:

- a. Good Glycemic control (target Hba1c < 7)
- b. Good B.P. Control (target < 130/80 mm of hg)
- c. Use of ACEI (such as lisinopril etc) or ARB (such as losartan Etc)
- d. Restrict excess dietary protein intake.

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e. Avoid NSAIDs.

Refer to CDE/RN and RD .

| | |
|------------------------|-------------------|
| Component | 5/7/2013 |
| Latest Ref Rng | |
| Microalbumin/creatinin | 58.6 (H) |
| e | <20.0 ug/mg creat |

In view of wide excursions , Pt will benefit from CGMS And hybrid insulin pump.
Patient drives school bus.
Diabetes and personal and public safety issues/implications regarding Driving , need to check
fingerstick glucosaprior to driving with goal > 100 d/w patient-questions answered .

Insulin long-term use

Insulin Injection Record
Sarah E Ford MRN: 1093909
10/17/2019

Meal Time Insulin Type: Novolog

| Blood Glucose (Mg/dl) | Breakfast | Lunch | Supper | Day Snack | Night Snack | Correction for High Glucose if not Eating Meal | Correction for High Glucose at Bedtime |
|-----------------------------|-----------|-------|--------|-----------|-------------|--|---|
|-----------------------------|-----------|-------|--------|-----------|-------------|--|---|

Less than 70
Treat low blood sugar with 15 grams carbohydrate
(example: 4 ounces juice or 4 glucose tablets),
recheck in 15 minutes and repeat treatment until above 70,
then take insulin in 70 - 90 row.

| | | | | | | | |
|-----------|----|----|----|----|----|----|----|
| 70 - 90 | 6 | 6 | 6 | 6 | 6 | 0 | 0 |
| 91 - 130 | 8 | 8 | 8 | 8 | 8 | 0 | 0 |
| 131 - 150 | 9 | 9 | 9 | 9 | 9 | 0 | 0 |
| 151 - 200 | 10 | 10 | 10 | 10 | 10 | 0 | 0 |
| 201 - 250 | 12 | 12 | 12 | 12 | 12 | 2 | 2 |
| 251 - 300 | 14 | 14 | 14 | 14 | 14 | 4 | 4 |
| 301 - 350 | 16 | 16 | 16 | 16 | 16 | 6 | 6 |
| 351 - 400 | 18 | 18 | 18 | 18 | 18 | 8 | 8 |
| 401 - 450 | 20 | 20 | 20 | 20 | 20 | 10 | 10 |
| Over 450 | 20 | 20 | 20 | 20 | 20 | 10 | 10 |

Do not give mealtime or correction insulin more frequently than every 3 hours.

Long-acting Insulin Toujeo ; 45 units Bedtime

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Carb consistent diet
Exercise daily.
Please check fingerstick glucose before each meal and bedtime and once a week At 2 am

2.h/o Primary Hypothyroidism:

Pt reports compliance with L-T4 75 mcg/d 6 days of week.

To recheck.

3. BMI : recent weight gain - BMI 30 (from 27)
4. Hyperlipidemia:

| | |
|----------------|------------|
| Component | LDL Direct |
| Latest Ref Rng | <100 mg/dL |
| 5/7/2013 | 139 (H) |

| | | | | | |
|------------------|-----------|----------------|-----------------|------------|-----|
| Component | 3/24/2014 | Latest Ref Rng | Cholesterol | <200 mg/dL | 176 |
| Triglycerides | 136 | <200 mg/dL | HDL Cholesterol | >40 mg/dL | 61 |
| LDL Cholesterol | 88 | <100 mg/dL | Non HDL | <130 mg/dL | 115 |
| VLDL Cholesterol | 27 | 16 - 42 mg/dl | Cholesterol | | |

For now ct diet /exercise

Pt does not have any immediate plans to start family -on OCP. Pregnancy contraindication d/w patient .

5. Medical aspect /health hazardsof ETOH consumption especially related to diabetes discussed with patient
. Propensity for severe potentially fatal hypoglycemia with ETOH and hyperglycemia (if consumed with excess Carbs) and reports of acidosis with excess ETOH consumption discussed with patient. Questions answered .

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Pt does not smoke tobacco or uses drugs . .

6. MRI 9/6/2019 (ct 4/3/20180 stable benign pineal cyst 1 cm

RTC 6 months . Midlevel f/u in 3 month

Electronically signed by Prashant Nadkarni V, MD at 10/17/2019 11:40 AM

END OF REPORT