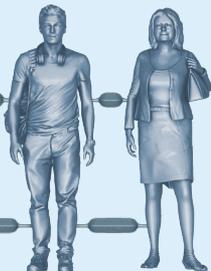


# Could Testogel<sup>®</sup> 16.2mg/g gel (testosterone) help him regain some of what he has lost?

Testogel 16.2 mg/g gel is indicated in adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests

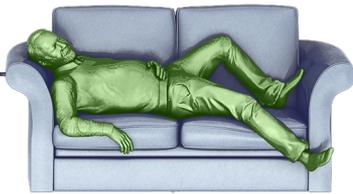


 **BESINS**  
HEALTHCARE  
Innovating for Well-being

**Testogel**  
(testosterone)  
16.2 mg/g gel 

# Symptoms

Guidelines suggest one or more of the following symptoms could be a sign of Testosterone Deficiency (TD).<sup>1,2</sup>



**Physical** symptoms can lead to a reduced quality of life.<sup>3,4</sup>

- Reduced bone density
- Reduced muscle mass and strength
- Gain in body fat

**Sexual** symptoms can lead to:<sup>3,4</sup>

- Low libido
- Difficulty achieving erections
- Breakdown in relationship



**Mental** symptoms can lead to a low satisfaction with life.<sup>3,4</sup>

- Depressed mood
- Fatigue or loss of energy
- Reduced self confidence

## Scale of the problem<sup>5</sup>

Identifying TD can be difficult as patients may find it hard to talk through their concerns and symptoms. A significant proportion of patients who suffer from the following conditions may also suffer from TD.

National\* and International\*\* guidelines suggest screening for TD in patients who suffer from diabetes, obesity and chronic opioid use.<sup>1-3</sup>

**TYPE II  
DIABETES**

50%

50% of men with type II diabetes may suffer from TD

**OBESITY**

52%

52% of men with BMI >30 kg/ m<sup>2</sup> may suffer from TD

**CHRONIC  
OPIOID USE**

53%

53% of men with chronic opioid use may suffer from TD

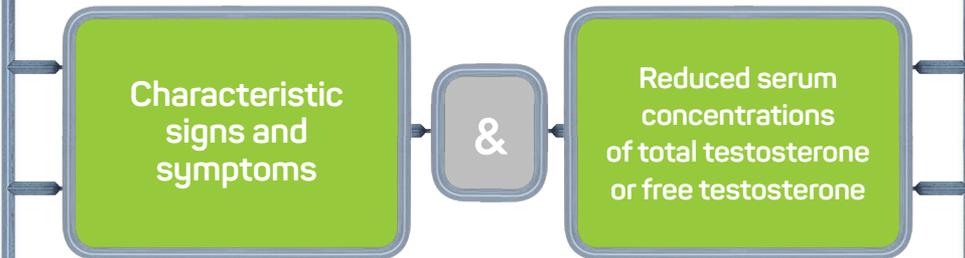
\*BSSM-British Society for Sexual Medicine \*\* AACE/ACE -The American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice

## Guidelines and screening

BSSM guidelines suggest screening for TD in men presenting with:<sup>1</sup>

- Consistent and multiple signs of TD<sup>6</sup>
- Erectile dysfunction (ED), loss of spontaneous erections or low sexual desire<sup>6</sup>
- Type 2 diabetes mellitus, BMI >30 kg/m<sup>2</sup> or waist circumference >102 cm (40.2 inches)<sup>6,7</sup>
- Long-term use of opiate, antipsychotic or anticonvulsant medication.<sup>6</sup>

### The elements of diagnosis



### Establishing signs and symptoms

A positive answer to questions 1 or 7 or a positive answer to any 3 other questions of the Androgen Deficiency in the Aging Male (ADAM) questionnaire. The ADAM questionnaire is a validated tool that can be used to assist in the identification of patients over 40 years of age with hypogonadism.<sup>8</sup>

**You can request a tear off pad of ADAM questionnaires from your Besins Healthcare representative for you to use with your patients to aid in the identification of the symptoms associated with TD.**

## ADAM Questionnaire

Your answers to the following questionnaire will help to identify whether you have the features of Testosterone Deficiency (TD).

Please answer the questions honestly.

	YES	NO
1. Do you have a decrease in libido (sex drive)?	<input type="checkbox"/>	<input type="checkbox"/>
2. Do you have a lack of energy?	<input type="checkbox"/>	<input type="checkbox"/>
3. Do you have a decrease in strength and /or endurance?	<input type="checkbox"/>	<input type="checkbox"/>
4. Have you lost height?	<input type="checkbox"/>	<input type="checkbox"/>
5. Have you noticed a decreased 'enjoyment of life'?	<input type="checkbox"/>	<input type="checkbox"/>
6. Are you sad and /or grumpy?	<input type="checkbox"/>	<input type="checkbox"/>
7. Are your erections less strong?	<input type="checkbox"/>	<input type="checkbox"/>
8. Have you noticed a recent deterioration in your ability to play sports?	<input type="checkbox"/>	<input type="checkbox"/>
9. Are you falling asleep after dinner?	<input type="checkbox"/>	<input type="checkbox"/>
10. Has there been a recent deterioration in your work performance?	<input type="checkbox"/>	<input type="checkbox"/>

Adapted from Morley JE et al. Metabolism 2000



### Reduced Serum concentrations of total testosterone or free testosterone

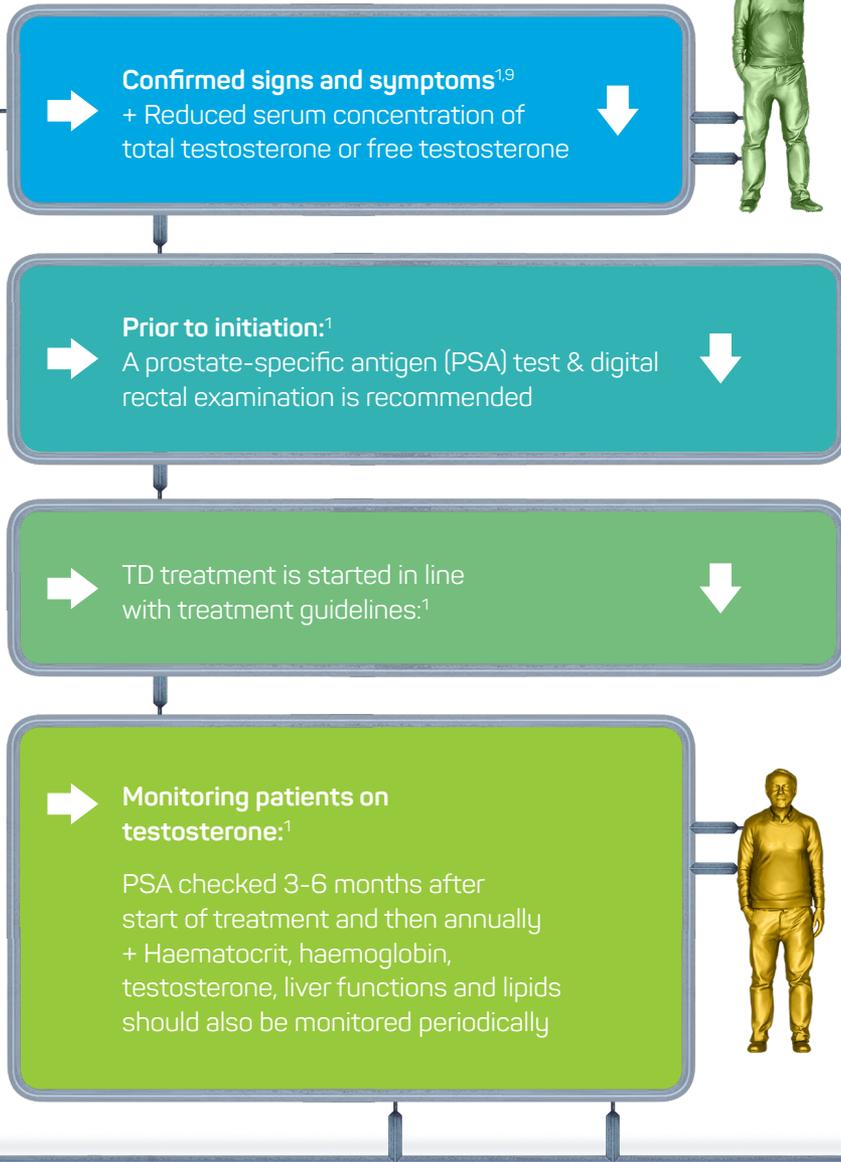
Biochemical assessment of TD through an early morning (7-11am) testosterone (T) blood test should be performed. This test should be performed with a reliable method, on at least 2 occasions, preferably 4 weeks apart. Fasting levels should be obtained where possible.<sup>6</sup>

### BSSM action levels\*

**Total T level <8 nmol/L or free T <0.180 nmol/L:** Usually requires T Therapy  
**Total T level >12 nmol/L or free T >0.225 nmol/L:** Does not require T Therapy  
**Total T 8-12 nmol/L or free T 0.180-0.225 nmol/L:** May require a trial of T Therapy for a minimum of 6 months based on symptoms

\*BSSM Guidelines state that reference ranges by laboratories represent the normal postulation and that action levels recommended by the BSSM refer to men with clinical symptoms of TD<sup>1</sup>

# Initiating and monitoring T Therapy\*



\* Please refer to prescribing information on the back of this piece for information on warnings, contraindications and advice to consider before initiating treatment with Testogel 16.2mg/g gel.

# Testogel® 16.2 mg/g gel

In an easy-to-use pump:<sup>9</sup>



The recommended dose is two actuations. The pump enables the prescriber to easily adjust the dose if required.\*<sup>9</sup>



Normal testosterone levels\*\* were achieved at day 182 in 82.2% (139/169) of hypogonadal men treated with an optimised dose, in a randomised placebo-controlled trial involving 274 patients.



Well tolerated: 1-10% of incidence of skin reactions.

Please refer to the prescribing information for further details regarding undesirable effects.



Comprehensive online support for patients that aims to instil confident, regular use of the treatment.



Besins Healthcare produced testosterone replacement (TR) gels are the number 1 in sales of TR therapies worldwide<sup>†‡</sup>

<sup>†</sup>this includes sales of Androgel in the USA<sup>10</sup> <sup>‡</sup>based on Q1 2019 sales

\*Testosterone levels should be monitored at baseline and at regular intervals during the above treatment. Clinicians should adjust the dosage depending on the clinical or laboratory response in individual patients.<sup>3</sup> \*\*In this study, a normal range was defined as a serum total testosterone average concentration of 300-1000ng/dL (10.4-34.7 nmol/L)<sup>11</sup>

## Dosing<sup>9</sup>

	Daily dose of Testogel 16.2 mg/g gel	No. actuations of Testogel 16.2 mg/g gel
Lowest daily dose	1.25g (20.25mg testosterone)	1 actuation
Recommended dose	2.5g (40.5mg testosterone)	2 actuations
Maximum dose	5.0g (81mg testosterone)	4 actuations

## Once-daily application<sup>9</sup>

The recommended dose is two actuations (40.5mg) of the pump



Apply Testogel 16.2 mg/g gel to upper arms and shoulders only

Recommended period between application and showering/bathing is 2 hours

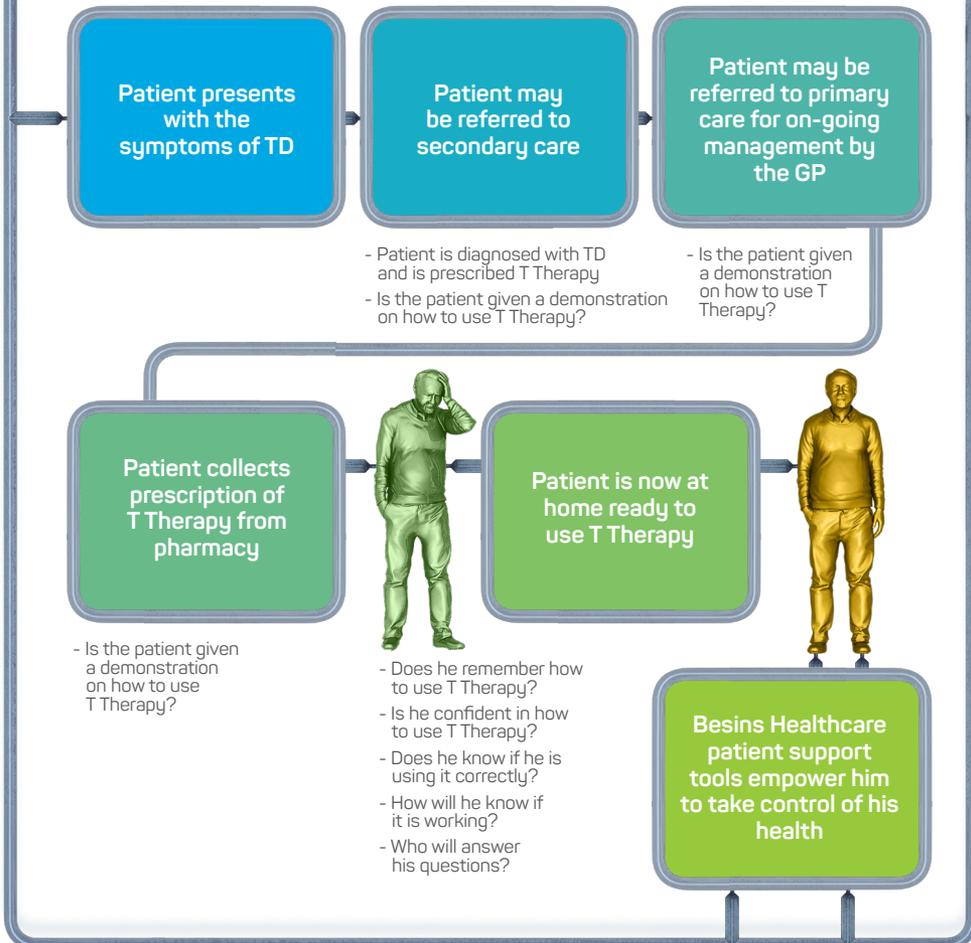


## Example patient journey to acquiring testosterone replacement therapy (T Therapy) for TD

Informing a patient that they have TD can be a daunting experience. Information given about treatment may not be taken fully on board at this unsettling time. Important information such as:

1. How to apply the treatment
2. How the treatment works
3. What side effects to look out for
4. That the effects of treatment may take 6 weeks to 3 years to improve<sup>12,13</sup>

If this information is not understood, it can lead to problems with compliance and ultimately the desired clinical outcome of treatment.<sup>12</sup>



## Patient compliance for better clinical outcomes

Enabling people to be more involved in their own health care is a key component of CCG's and NHS England's statutory duties. To help support this requirement, patients prescribed Testogel 16.2m/g gel have access to dedicated support tools: the Testogel 16.2mg/g gel website, patient information leaflet and mobile app (coming soon).<sup>12-16</sup>

### Besins Healthcare support tools help patients:

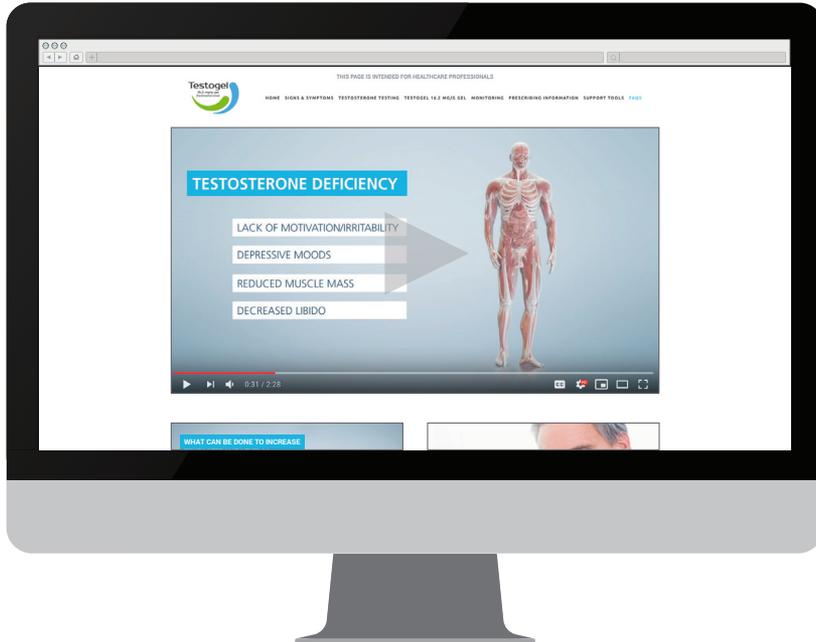
- become more involved in their T Therapy
- better understand their treatment
- feel reassured
- feel confident in their T Therapy
- to be in control of their health



In addition to the benefits for patients, Besins Healthcare's support tools may also reduce the burden on NHS resources, by providing patients an additional source of information.

Besins Healthcare website and support tools can provide patients with the information they need to feel confident and in control of their medication and health leading to improved patient compliance.<sup>14,15</sup>

Visit us on [www.testogelpump.co.uk](http://www.testogelpump.co.uk)  
to find more information on Testogel 16.2mg/g gel



### For HCPs

- Information on TD
- HCP specific FAQ's
- Prescribing Testogel 16.2mg/g gel
- Monitoring
- Support tools

### For patients

- What is testosterone deficiency
- Why you need testosterone
- How to use Testogel 16.2mg/g gel
- How the treatment works
- FAQ's

## PRESCRIBING INFORMATION TESTOGEL®(testosterone)

16.2 MG/G, GEL

For full prescribing information, including side effects, precautions and contraindications, please consult the Summary of Product Characteristics (SPC). **Presentation:** Transdermal gel in a multi-dose container, one pump actuation delivers 1.25 g of gel containing 20.25 mg of testosterone. **Indication:** Testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. **Dosage and administration:** Cutaneous use. The recommended dose is two pump actuations of gel (i.e. 40.5 mg of testosterone) applied once daily. The daily dose should not exceed four pump actuations (81 mg testosterone) per day. Adjustment of dosage should be achieved by increments of one pump actuation, usually based on measurements of blood testosterone levels and/or clinical response. The gel should be administered by the patient himself, onto clean, dry, healthy skin on the right and left upper arms and shoulders. Allow to dry for at least 3-5 minutes before dressing. **Contraindications:** Cases of known or suspected cancer of the prostate or breast, known hypersensitivity to testosterone or to any other constituent of the gel. **Warnings and precautions for use:** Testosterone insufficiency should be clearly demonstrated by clinical features and confirmed by 2 separate blood testosterone measurements. Testosterone levels should be monitored at baseline and at regular intervals during treatment. In addition, in patients receiving long-term androgen treatment the following laboratory parameters should be checked regularly: haemoglobin, haematocrit (to detect polycythaemia), liver function tests, lipid profile. Testogel may affect results of laboratory tests of thyroid function. Risk of pre-existing prostatic cancer should be excluded and the prostate gland and breast monitored during Testogel treatment. Androgens may accelerate the progression of sub-clinical prostate cancer and benign prostate hyperplasia. Testogel should be used with caution in cancer patients at risk of hypercalcaemia and associated hypercalcaemia due to bone metastases; regular monitoring of blood calcium levels is recommended in these patients. Testogel may cause oedema with or without congestive cardiac failure in patients suffering from severe cardiac, hepatic or renal insufficiency or ischaemic heart disease. If this occurs, treatment must be stopped immediately. Testogel should be used with caution in patients with ischaemic heart disease. Testosterone may cause a rise in blood pressure and should be used with caution in men with hypertension. Testogel should be used with caution in patients with thrombophilia. There are published reports of increased risk of sleep apnoea in hypogonadal subjects treated with testosterone esters, especially in those with risk factors such as obesity and chronic respiratory disease. Spermatogenesis may be suppressed leading to adverse effects on semen parameters. Gynecomastia occasionally develops and occasionally persists. Irritability, nervousness, weight gain, prolonged or frequent erections may indicate excessive androgen exposure requiring dosage adjustment. Testogel should be used with caution in patients with epilepsy and migraine. Do not apply to the genital areas as the high alcohol content may cause local irritation. Testogel can be transferred to other persons by close skin to skin contact. There is limited experience regarding safety and efficacy of Testogel in patients over 65 years of age. Testogel is not indicated for use in women or in children under 18 years of age. Testogel is not a treatment for male impotence or sterility. For further details refer to the SPC. **Interactions:** May increase the activity of oral anticoagulants. Concomitant administration of testosterone and ACTH or corticosteroids may increase the risk of developing oedema. May cause changes in insulin sensitivity, glucose intolerance, glycaemic control, blood glucose and glycosylated haemoglobin levels. **Pregnancy and lactation:** Pregnant women must avoid any contact with Testogel application sites. This product may have adverse virilising

effects on the foetus. **Undesirable effects:** Local skin reactions include: acne, alopecia, dry skin, skin lesions, contact dermatitis, hair colour changes, rash, sweating, hypertrichosis, application site hypersensitivity, application site pruritus. The following commonly ( $\geq 1/100$ ;  $< 1/10$ ) occur with Testogel: emotional symptoms, prostate specific antigen (PSA) increased, increased haematocrit, increased haemoglobin and increased red blood cell count. The following uncommonly ( $\geq 1/1000$  to  $< 1/100$ ) occur with Testogel: malignant hypertension, flushing, phlebitis, diarrhoea, abdominal distention, oral pain, gynaecomastia, nipple disorder, testicular pain, increased erection and pitting oedema. Other known adverse drug reactions: testis disorder, headache, dizziness, paraesthesia, vasodilation (hot flushes), deep vein thrombosis, dyspnoea, polycythaemia, anaemia, musculoskeletal pain, prostate enlargement, oligospermia, benign prostate hyperplasia, impaired urination, anxiety, depression, aggression, insomnia, nausea, asthenia, oedema, malaise and weight increase. In case of severe application site reactions, treatment should be reviewed and discontinued if necessary. **NHS Price:** £31.11 per 88g pump pack. **Legal category:** POM. **Marketing Authorisation Number:** PL 28397/0007. **Marketing Authorisation Holder:** Besins Healthcare, Avenue Louise, 287, Brussels, Belgium. **Date of preparation of Prescribing Information:** 06 September 2019 TES/2019/063

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Besins Healthcare (UK) Ltd Drug Safety on 0203 862 0920 or Email: [pharmacovigilance@besins-healthcare.com](mailto:pharmacovigilance@besins-healthcare.com)

TES/2019/056 Date of preparation: September 2019

### References:

1. BSSM guidelines on adult testosterone deficiency. *J Sex Med* 2017;14:1504-23.
2. ACEE/ACE Obesity CPG, *Endocr Pract.* 2016;22(Suppl 3)
3. The Endocrine Society's Clinical Guidelines: Testosterone therapy in adult men with androgen deficiency syndromes. 2010. Available at: <https://academic.oup.com/jcem/article/95/6/2536/2597900> Accessed: February 2018.
4. Lunenfeld B et al. *Aging Male* 2013; 16: 143-150.
5. Khera M et al. *J Sex Med* 2016; 13: 1787-1804
6. Hackett G, et al. British Society for Sexual Medicine Guidelines on Adult Testosterone Deficiency, With Statements for UK Practice. *J Sex Med* 2017;14:1504-1523
7. Garvey, TW et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for Comprehensive Medical Care of Patients with Obesity. Available at: <https://www.aace.com/files/guidelines/ObesityExecutiveSummary.pdf> Accessed February 2019.
8. Morley JE et al. *Metabolism* 2000. Vol 49:1239-9.
9. Testogel® 16.2 mg/g Summary of Product Characteristics, July 2018 1242 10. Data on file (TES/2018/114)
11. Kaufman JM et al. *J Sex Med.* 2012; 9(4): 1149-1161
12. Long-Term Treatment Patterns of Testosterone Replacement Medications Craig Donatucci, MD, Zhanlin Cui, PhD,\*Yun Fang, MS, and David Muram, MD DOI: 10.1111/jsm.12608 13. Compliance session Sept 2019- Besins Healthcare
14. Involving people in their own health and care: Statutory guidance for clinical commissioning groups and NHS England (<https://www.england.nhs.uk/wp-content/uploads/2017/04/ppp-involving-people-health-care-guidance.pdf>)
15. Computer-based Approaches to Patient Education: A Review of the Literature Deborah Lewis, EDD, RN, CDE 16. Supporting Patient Education Besins Healthcare