Pancreatic Adenocarcinoma

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**Note:** Consider Clinical Trials as treatment options for eligible patients

---

**CLINICAL PRESENTATION**

- Clinical suspicion of pancreatic cancer (e.g., jaundice) or evidence of dilated pancreatic duct and/or bile duct stricture

**DIAGNOSTIC WORK-UP AND TISSUE ACQUISITION**

- **Mass in pancreas on imaging?**
  - Yes
    - Metastases?
      - Yes
        - CT scan or ultrasound-guided biopsy of metastatic disease if accessible. Core needle biopsy with FNA is preferred whenever technically feasible to facilitate next generation sequencing (NGS).
        - Germline testing
        - Discuss Goal Concordant Care (GCC) with patient or if clinically indicated, with Patient Representative
      - No
        - Multidisciplinary planning presentation
        - EUS with FNA
        - Liver function tests, CA 19-9
        - CT chest (preferred) or chest x-ray
        - Germline testing
        - Discuss GCC with patient or if clinically indicated, with Patient Representative
  - No
    - Pancreatic CT scan protocol
      - Lifestyle risk assessment

- **Biopsy or brushings positive?**
  - Yes
    - Surgical consult
  - No
    - Multidisciplinary planning presentation
    - Liver function tests, CA 19-9
    - CT chest (preferred) or chest x-ray
    - EUS with FNA if mass visualized in pancreas
    - ERCP with brushings as clinically indicated
    - Discuss GCC with patient or if clinically indicated, with Patient Representative

---

**EUS** = endoscopic ultrasound

**FNA** = fine needle aspiration

**ERCP** = endoscopic retrograde cholangiopancreatography

1 Pancreatic CT scan protocol: multiphasic cross sectional imaging and thin slices; consider MRI, PET and/or EUS if CT results are equivocal

2 For patients who cannot undergo contrast enhanced CT (allergy, renal issues, etc.) consider MRI as an alternative

3 See **Physical Activity, Nutrition, and Tobacco Cessation Treatment** algorithms; ongoing reassessment of lifestyle risks should be a part of routine clinical practice

4 Consider referral to Genetic Counseling

5 GCC should be initiated by the Primary Oncologist. If Primary Oncologist is unavailable, Primary Team/Attending Physician to initiate GCC discussion and notify Primary Oncologist. Patients, or if clinically indicated, the Patient Representative should be informed of therapeutic and/or palliative options. GCC discussion should be consistent, timely, and re-evaluated as clinically indicated. The Advance Care Planning (ACP) note should be used to document GCC discussion. Refer to GCC home page (for internal use only).

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Pancreatic Adenocarcinoma

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Note: Consider Clinical Trials as treatment options for eligible patients

PRESENTATION

Resectable\(^1\) pancreatic cancer and low-risk\(^2\) clinical features

TREATMENT

- Pre-operative clinical trial (preferred) or Systemic therapy\(^3\)
- Consider radiation therapy\(^4\) in select patients

Post-treatment restaging

Evidence of locally advanced and/or metastatic disease?

Yes

- Individualized subsequent therapy
- Consider best supportive care as indicated

No

Resection

Adequate and uneventful post-operative recovery within 12 weeks\(^5\):

- Consider adjuvant chemotherapy\(^6\) based on duration and response to neoadjuvant chemotherapy
- Consider chemoradiation therapy\(^4\) if not previously given

Resection\(^7\)

Adequate and uneventful post-operative recovery within 12 weeks\(^5\):

- Restaging CT\(^8,9\) scan
- CA 19-9
- Adjuvant gemcitabine or fluorouracil-based chemotherapy\(^6\)
- Consider radiation therapy\(^4\) in the setting of an R1 resection

1 Resectable is defined as:
- Patent superior mesenteric vein-portal vein (SMV-PV) confluence
- No interface between tumor and superior mesenteric artery (SMA) or celiac
- No metastases

2 Low-risk features:
- No suspicion of metastatic disease
- CA 19-9 ≤ 500 units/mL with normal bilirubin
- Manageable and optimized comorbidities

3 Typically gemcitabine plus paclitaxel protein-bound or FOLFIRINOX (see Appendix A – Chemotherapy Regimens)

4 See Appendix B – Radiation Therapy

5 If post-operative recovery is > 12 weeks, adjuvant therapy will be at the discretion of the treating provider

6 Typically FOLFRINOX or GemCape or single agent gemcitabine (see Appendix A – Chemotherapy Regimens)

7 If patient exhibits all low-risk features and all other factors are favorable, primary resection can be considered

8 For patients who cannot undergo contrast enhanced CT (allergy, renal issues, etc.) consider MRI as an alternative

9 Pancreatic CT scan protocol: multiphasic cross sectional imaging and thin slices; consider MRI, PET and/or EUS if CT results are equivocal
Pancreatic Adenocarcinoma

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Note: Consider Clinical Trials as treatment options for eligible patients

PRESENTATION

Resectable pancreatic cancer and high-risk clinical features

- Elevated CA 19-9 and/or other clinical indications of metastatic disease
- Metastases?
  - Yes
    - Pre-operative clinical trial preferred
    - Systemic chemotherapy with radiation therapy in select patients
    - Restage after each treatment modality
  - No
    - Characterize/optimize comorbidities; diet and exercise recommended

Is staging laparoscopy appropriate?

- Yes
  - Staging laparoscopy positive for metastatic disease?
    - Yes
      - Follow metastatic section on Page 7
    - No
      - Adequate and uneventful postoperative recovery within 12 weeks:
        - Consider adjuvant chemotherapy based on duration and response to neoadjuvant chemotherapy
  - No
    - Resection

Staging laparoscopy positive for metastatic disease?

Follow metastatic section on Page 7

TREATMENT

Characterize/optimize comorbidities; diet and exercise recommended

1. Resectable is defined as:
   - Patent superior mesenteric vein-portal vein (SMV-PV) confluence
   - No interface between tumor and superior mesenteric artery (SMA) or celiac
   - No metastases

2. High-risk features:
   - Suspicion of metastatic disease
   - CA 19-9 > 500 units/mL with a normal bilirubin
   - Reversible and optimizable comorbidities

3. Typically gemcitabine plus paclitaxel protein-bound or FOLFIRINOX (see Appendix A – Chemotherapy Regimens)

4. See Appendix B – Radiation Therapy

5. If post-operative recovery is > 12 weeks, adjuvant therapy will be at the discretion of the treating provider

6. Typically FOLFIRINOX or GemCape or single agent gemcitabine (see Appendix A – Chemotherapy Regimens)

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**Presenting:**

- Clinical trial (preferred) or systemic therapy followed by radiation therapy (in select patients) if no evidence of progression and/or metastatic disease on interval scanning.

**Treatment:**

- Multidisciplinary planning presentation and consider surgical resection for resectable pancreatic cancer.
- Clinical trial preferred.

**Note:** Consider Clinical Trials as treatment options for eligible patients.

---

<table>
<thead>
<tr>
<th>Borderline resectable pancreatic cancer^1</th>
<th>Clinical trial preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-treatment restaging</td>
<td>Clinical trial preferred</td>
</tr>
<tr>
<td>Radiographic, and/or biochemical, and/or clinical evidence of disease progression?</td>
<td></td>
</tr>
</tbody>
</table>

Yes

- For subsequent therapy options for management of progressed/metastatic disease, see Page 7

No

- After resection, consider adjuvant chemotherapy^4 based on duration and response to neoadjuvant therapy
- Resection?
  - Yes
  - For subsequent therapy options for management of progressed/metastatic disease, see Page 7
  - No

---

^1 MD Anderson Cancer Center’s definition for **borderline resectable pancreatic cancer with or without high risk features:**

Based on anatomic considerations; a tumor abutment of ≤180° of circumference of superior mesenteric artery (SMA); short-segment encasement abutment of the common hepatic artery or gastroduodenal artery; short-segment occlusion of superior mesenteric vein (SMV) or superior mesenteric vein-portal vein (SMV-PV) and patent vessel above and below.

High-risk features:
- Suspicion of metastatic disease
- CA 19-9 > 500 units/mL with a normal bilirubin
- Reversible and optimizable comorbidities

^2 Typically gemcitabine plus paclitaxel protein-bound or FOLFIRINOX (see Appendix A – Chemotherapy Regimens)

^3 See Appendix B – Radiation Therapy

^4 Typically FOLFIRINOX or GemCape or single agent gemcitabine (see Appendix A – Chemotherapy Regimens)
Locally advanced pancreatic cancer

**PRESENTATION**

- Clinical trial (preferred) or
- First line systemic therapy

Serial post-treatment restaging for 4-6 months or as indicated per protocol

- No metastasis and
- No further local progression

**TREATMENT**

- Consider:
  - Systemic therapy\(^3\) or
  - Radiation therapy\(^4\) in select patients or
  - Observation

Local progression only

- Radiation therapy\(^4\) (if not previously delivered) or
- Systemic therapy\(^3\) or
- Best supportive care

Metastasis

- Subsequent therapy\(^1\) or
- Best supportive care

\(^1\) Locally advanced defined as:
- Interface between tumor and SMA or celiac > 180°
- Interface with aorta
- Unresectable venous occlusion

\(^2\) Typically gemcitabine plus paclitaxel protein-bound or FOLFIRINOX (see Appendix A – Chemotherapy Regimens)

\(^3\) See Appendix A – Chemotherapy Regimens

\(^4\) See Appendix B – Radiation Therapy

Note: Consider Clinical Trials as treatment options for eligible patients

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Pancreatic Adenocarcinoma

Note: Consider Clinical Trials as treatment options for eligible patients

RECURRENT

Local disease only at time of recurrence

Previous radiation therapy?

Yes

No

Symptoms associated to recurrence?

Yes

No

TREATMENT

Systemic chemotherapy\(^1\)

Consider radiation therapy\(^2\)

Individualized surveillance

Systemic chemotherapy\(^1\) and subsequent radiation therapy\(^2\) as clinically indicated

\(^1\) See Appendix A – Chemotherapy Regimens

\(^2\) See Appendix B – Radiation Therapy
Pancreatic Adenocarcinoma

**PRESENTATION**

- **Metastatic disease at presentation**
  - **Good performance status (ECOG 0-1)**
    - Clinical trial (preferred)
    - FOLFIRINOX\(^1\) if ECOG performance status 0-1
    - Gemcitabine plus paclitaxel protein-bound if ECOG performance status 0-2\(^2\)
    - Other gemcitabine doublet if ECOG performance status 0-1
  - **Poor performance status (ECOG ≥ 2)**
    - Best supportive care if ECOG performance status > 2 or Gemcitabine if ECOG performance status 2

**Metastatic disease after primary treatment**

- **Good performance status (ECOG 0-1)**
  - Subsequent therapy:
    - Clinical trial (preferred)
    - After gemcitabine-based therapy\(^1\):
      - Liposomal irinotecan plus fluorouracil\(^1\) or FOLFIRINOX\(^1\) or mFOLFOX6\(^1\) or XELOX\(^1\)
    - After FOLFIRINOX-based therapy\(^1\):
      - Gemcitabine plus paclitaxel protein-bound or other gemcitabine doublet except gemcitabine plus fluorouracil

- **Poor performance status (ECOG ≥ 2)**
  - Best supportive care

**TREATMENT**

- Individualized surveillance or Additional treatment as clinically indicated or Olaparib\(^3\)

---

**ECOG** = Eastern Cooperative Oncology Group

\(^1\) See Appendix A – Chemotherapy Regimens

\(^2\) For patient with ECOG performance status 2, modify dose as appropriate (refer to dosing for average performance status in Appendix A)

\(^3\) Olaparib may be used as maintenance treatment in the setting of platinum sensitive tumors with BRCA family mutations and no disease progression during at least 16 weeks of first-line, platinum-based chemotherapy
SURVEILLANCE
(For patients who had surgery as primary treatment)

<table>
<thead>
<tr>
<th>Every 6 months for a total of 5 years, then annually for a total of 5 years</th>
<th>Physical Examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>First 3 years: Perform every 6 months</td>
<td>● Surveillance (portal venous phase) CT(^1,2) abdomen</td>
</tr>
<tr>
<td></td>
<td>● Chest x-ray</td>
</tr>
<tr>
<td></td>
<td>● CA 19-9</td>
</tr>
<tr>
<td>≥ Years 3:</td>
<td>For surveillance recommendations, see Survivorship – Pancreatic Cancer algorithm</td>
</tr>
</tbody>
</table>

\(^1\) Consider dedicated pancreatic CT protocol, MRI, PET and/or EUS if surveillance CT results are equivocal, e.g., suspicion of recurrence within pancreatic remnant, extrapancreatic local recurrence, question of liver metastases, etc.

\(^2\) For patients who cannot undergo contrast enhanced CT (allergy, renal issues, etc.) consider MRI as an alternative
**Pancreatic Adenocarcinoma**

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**BILIARY OBSTRUCTION**

- Biliary obstruction
  - Pancreatic CT\(^1\) scan protocol
  - Biopsy confirmed adenocarcinoma?\(^2\)
    - Yes
      - ERCP with insertion of a plastic or metal biliary stent
    - No or Uncertain
      - ERCP with insertion of a plastic or metal biliary stent
      - Metastases?
        - Yes
          - ERCP with insertion of a biliary stent(s)\(^2\) if biliary system can be drained
        - No
          - ERCP with insertion of plastic stent until biopsy confirmation of malignancy
          - If insertion not technically possible, percutaneous biliary drain with attempt to subsequently insert indwelling plastic or expandable metal stent

**MECHANICAL GASTRIC OUTLET OBSTRUCTION**

- Mechanical gastric outlet obstruction
  - Life expectancy > 3 months or non-extensive metastases?
    - Yes
      - Surgical risk
        - High\(^3\)
          - Duodenal stent with or without radiation therapy
        - Low
          - Surgical bypass
    - No
      - Duodenal stent with or without radiation therapy
      - Duodenal stent and/or venting gastrostomy tube

---

ERCP = endoscopic retrograde cholangiopancreatography

\(^1\) For patients who cannot undergo contrast enhanced CT (allergy, renal issues, etc.) consider MRI as an alternative

\(^2\) Biliary stent(s) may be metal or plastic

\(^3\) Presence of comorbidities and malnutrition

Note: Consider Clinical Trials as treatment options for eligible patients

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## APPENDIX A: Chemotherapy Regimens

### Gemcitabine-based regimens1,2,3:

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Description</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemcitabine</td>
<td>Gemcitabine 600-750 mg/m² IV on Days 1, 8, 15 (fixed dose infusion rate of 10 mg/m²/minute preferred)</td>
<td>Repeat every 28 days</td>
</tr>
<tr>
<td>GemCis - gemcitabine and cisplatin5</td>
<td>Gemcitabine 600-750 mg/m² IV on Day 1 (fixed dose infusion rate of 10 mg/m²/min preferred)</td>
<td>Repeat every 14 days</td>
</tr>
<tr>
<td>GemCape - gemcitabine and capecitabine4</td>
<td>Gemcitabine 600-750 mg/m² IV on Days 1 and 8 (fixed dose infusion rate of 10 mg/m²/minute preferred)</td>
<td>Repeat every 21 days</td>
</tr>
</tbody>
</table>

### Gemcitabine plus paclitaxel protein-bound (Abraxane6)7

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Description</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemcitabine plus paclitaxel protein-bound (Abraxane6)7</td>
<td>Paclitaxel protein-bound 100-125 mg/m² IV on Days 1, 8, 15</td>
<td>Repeat every 28 days</td>
</tr>
<tr>
<td>Gemcitabine 600-750 mg/m² IV on Days 1, 8, 15 (fixed dose infusion rate of 10 mg/m²/min preferred)</td>
<td>Repeat every 28 days</td>
<td></td>
</tr>
</tbody>
</table>

### Average performance status:

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Description</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>GemCis - gemcitabine and cisplatin5</td>
<td>Gemcitabine 600-750 mg/m² IV on Days 1, 8, 15 (fixed dose infusion rate of 10 mg/m²/min preferred)</td>
<td>Repeat every 14 days</td>
</tr>
<tr>
<td>GemCape - gemcitabine and capecitabine4</td>
<td>Gemcitabine 600-750 mg/m² IV on Days 1 and 8 (fixed dose infusion rate of 10 mg/m²/minute preferred)</td>
<td>Repeat every 21 days</td>
</tr>
<tr>
<td>GemCape - gemcitabine and capecitabine4 (dosing from ESPAC-4 in the adjuvant setting)</td>
<td>Gemcitabine 1,000 mg/m² IV over 30 minutes weekly on Days 1, 8, and 15</td>
<td>Repeat every 28 days</td>
</tr>
<tr>
<td>GemCape - gemcitabine and capecitabine4 (dosing from ESPAC-4 in the adjuvant setting)</td>
<td>Gemcitabine 1,000 mg/m² IV over 30 minutes weekly on Days 1, 8, and 15</td>
<td>Repeat every 28 days</td>
</tr>
<tr>
<td>GemCape - gemcitabine and capecitabine4 (dosing from ESPAC-4 in the adjuvant setting)</td>
<td>Gemcitabine 1,000 mg/m² IV over 30 minutes weekly on Days 1, 8, and 15</td>
<td>Repeat every 28 days</td>
</tr>
</tbody>
</table>

### GTX

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Description</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>GTX</td>
<td>Gemcitabine 300-400 mg/m² IV on Days 4 and 11 (fixed dose infusion rate of 10 mg/m²/minute preferred)</td>
<td>Repeat every 21 days</td>
</tr>
<tr>
<td>Docetaxel 30-40 mg/m² IV on Days 4 and 11</td>
<td>Repeat every 21 days</td>
<td></td>
</tr>
<tr>
<td>Capcitabine 1,000 mg/m²/day PO divided twice daily on Days 1-14</td>
<td>Repeat every 21 days</td>
<td></td>
</tr>
</tbody>
</table>

### GemOx - gemcitabine and oxaliplatin

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Description</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>GemOx - gemcitabine and oxaliplatin</td>
<td>Gemcitabine 600-750 mg/m² IV on Day 1 (fixed dose infusion rate of 10 mg/m²/minute preferred)</td>
<td>Repeat every 14 days</td>
</tr>
<tr>
<td>Oxaliplatin 85 mg/m² IV over 2 hours on Day 1</td>
<td>Repeat every 14 days</td>
<td></td>
</tr>
</tbody>
</table>

### Fluoropyrimidine-based regimens1,2:

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Description</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>mFOLFOX 6</td>
<td>Oxaliplatin 85 mg/m² IV over 2 hours on Day 1</td>
<td>Repeat every 14 days</td>
</tr>
<tr>
<td>Leucovorin 400 mg/m² IV over 2 hours on Day 18</td>
<td>Repeat every 14 days</td>
<td></td>
</tr>
<tr>
<td>Fluorouracil 400 mg/m² IV bolus on Day 16, then fluorouracil 2,400 mg/m² IV continuous infusion over 46 hours</td>
<td>Repeat every 14 days</td>
<td></td>
</tr>
</tbody>
</table>

### FOLFIRINOX4,2

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Description</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOLFIRINOX4,2</td>
<td>Oxaliplatin 75-85 mg/m² IV over 2 hours on Day 1</td>
<td>Repeat every 14 days</td>
</tr>
<tr>
<td>Leucovorin 250-300 mg/m² IV over 90 minutes on Day 1</td>
<td>Repeat every 14 days</td>
<td></td>
</tr>
<tr>
<td>Leucovorin 400 mg/m² IV over 2 hours on Day 17</td>
<td>Repeat every 14 days</td>
<td></td>
</tr>
<tr>
<td>Fluorouracil 400 mg/m² IV bolus on Day 1, then fluorouracil 2,400 mg/m² IV continuous infusion over 46 hours</td>
<td>Repeat every 14 days</td>
<td></td>
</tr>
</tbody>
</table>

### Liposomal irinotecan (Onivyde®) plus 5-fluorouracil10

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Description</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liposomal irinotecan 70 mg/m² IV over 90 minutes on Day 110</td>
<td>Repeat every 14 days</td>
<td></td>
</tr>
<tr>
<td>Leucovorin 400 mg/m² IV over 2 hours on Day 17,8</td>
<td>Repeat every 14 days</td>
<td></td>
</tr>
<tr>
<td>Fluorouracil 400 mg/m² IV bolus on Day 17,8, then Fluorouracil 2,400 mg/m² IV continuous infusion over 46 hours</td>
<td>Repeat every 14 days</td>
<td></td>
</tr>
</tbody>
</table>

1 For gemcitabine-based and fluorouracil-based regimen, combination chemotherapy is preferred over monotherapy in the preoperative setting
2 Dosing should be started at the lower level and modified as patient tolerates
3 If fixed dose infusion rate is not utilized, administer gemcitabine 1,000 mg/m² over 30 minutes
4 Typical post-operative adjuvant regimens: FOLFIRINOX or GemCape or single-agent gemcitabine (depending on response and recovery)
5 The preferred doublet for tumors with germline BRCA mutations
6 Many MD Anderson GI Oncologists omit Day 15 of gemcitabine and week three of capecitabine
7 Typical pre-operative neoadjuvant regimens: gemcitabine plus paclitaxel protein-bound or FOLFIRINOX
8 Many MD Anderson GI Oncologists omit the bolus of fluorouracil/leucovorin
9 FDA approved for the treatment of metastatic adenocarcinoma of the pancreas in combination with fluorouracil and leucovorin
10 For patients with known homozygous UGT1A1*28 allele reduce the initial starting dose to 50 mg/m²

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# APPENDIX B: Radiation Therapy

## Chemoradiation Regimens

### Long course chemoradiation
- Total dose 50 Gy in 25 fractions or 50.4 Gy in 28 fractions
- Concurrent capecitabine $1,650 \text{ mg/m}^2 \text{ PO in two divided doses on each day of radiation}$ or
- Concurrent gemcitabine 300-400 mg/m$^2$ IV given at fixed dose infusion once weekly

### Short course chemoradiation
- Total dose 30 Gy in 10 fractions
- Concurrent capecitabine $1,650 \text{ mg/m}^2 \text{ PO in two divided doses on each day of radiation}$ or
- Concurrent gemcitabine 300-400 mg/m$^2$ IV given at fixed rate dose infusion once weekly

### Hypofractionated chemoradiation
- Total dose 60-67.5 Gy in 15 fractions
- Concurrent capecitabine $1,650 \text{ mg/m}^2 \text{ PO in two divided doses on each day of radiation}$
- Requires image guidance

### Stereotactic Body Radiation Therapy
- Total dose 33-40 Gy in 5 fractions
- Usually requires fiducials
- Requires daily image guidance

---

1 Infusional fluorouracil may be used instead
2 If fixed dose infusion rate of 10 mg/m$^2$/minute not utilized, administer gemcitabine over 30 minutes
SUGGESTED READINGS


Continued on next page
SUGGESTED READINGS - continued


MD Anderson Institutional Policy #CLN1202 - Advance Care Planning Policy


Continued on next page
SUGGESTED READINGS - continued


Pancreatic Adenocarcinoma

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DEVELOPMENT CREDITS

This practice algorithm is based on majority expert opinion of the Gastrointestinal Center providers at the University of Texas MD Anderson Cancer Center. It was developed using a multidisciplinary approach that included input from the following:

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