

《攝護腺癌抗癌藥物治療指引》

Men with ADT-naïve, Metastatic Disease

ADT + one of the following

藥品名*	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Abiraterone	1000 mg PO		QD AC		13

藥品名*	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Apalutamide	240 mg PO		QD		14

ADT + Docetaxel + one of the following

藥品名*	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Abiraterone	1000 mg PO		QD AC		13

藥品名*	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Darolutamide	600 mg PO		BID		15

Docetaxel without Prednisolone with ADT

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Docetaxel	75	1	Q3W	6	1

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Docetaxel	30	1	QW		3

Men with Symptomatic mCRPC

First-line Therapy

Docetaxel with/without prednisolone

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Docetaxel	75	1	Q3W	6	1
Prednisolone	5 mg PO BID				

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Docetaxel	30	1	QW		3
Prednisolone	5 mg PO BID				

Alternative chemotherapy

Cabazitaxel + Prednisolone

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Cabazitaxel	20-25	1	Q3W	10	4, 5
Prednisolone	10 mg PO QD				

Enzalutamide

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Enzalutamide	160 mg PO QD				9

Abiraterone + Prednisolone

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Abiraterone	1000 mg PO QD	1			7, 8
Prednisolone	5 mg PO BID	1			

Mitoxantrone + Prednisolone

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Mitoxantrone	12	1	Q3W	10	2
Prednisolone	5 mg PO BID				

Pembrolizumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Pembrolizumab	200 mg	1	Q3W		6

Olaparib (For HRRm)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Olaparib	400 (150-300) mg PO BID				10, 12

Rucaparib (For BCRAm)

藥品名*	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Rucaparib	600 mg PO BID				11

Niraparib + Abiraterone + Prednisone (For BCRAm)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Niraparib	200 mg PO QD				16
Abiraterone	1000 mg PO QD				
Prednisone	5 mg PO BID				

Olaparib + Abiraterone + Prednisone (For BCRAm)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Olaparib	300 mg PO BID				17
Abiraterone	1000 mg PO QD				
Prednisone	5 mg PO BID				

Talazoparib + Enzalutamide + Prednisone (For BCRAm)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Talazoparib	0.5 mg PO QD				18
Enzalutamide	1000 mg PO QD				
Prednisone	5 mg PO BID				

*三院有個別版本

參考文獻

1. Jae Ho Jeong , Hyejung Hyun , In Gab Jeong, et al. Randomized phase II trial of docetaxel plus prednisolone with or without androgen deprivation treatment in castration-resistant prostate cancer. *Journal of Clinical Oncology* 2016; 34(2): 217-217.
2. Tannock IF, de Wit R, Berry WR, et al. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer. *N Engl J Med* 2004;351:1502-1512.
3. Kojima T, Shimazui T, Onozawa M. et al. Weekly Administration of Docetaxel in Patients with Hormone refractory Prostate Cancer: a Pilot Study on Japanese Patients. *Jpn J Clin Oncol.* 2004; 34(3): 137-41.
4. de Bono JS, Oudard S, Ozguroglu M, et al. Prednisone plus cabazitaxel or mitoxantrone for metastatic castration-resistant prostate cancer progressing after docetaxel treatment: a randomised open-label trial. *Lancet* 2010;376:1147-1154.
5. Eisenberger M, Hardy-Bessard AC1, Kim CS, et al. Phase III Study Comparing a Reduced Dose of Cabazitaxel (20 mg/m2) and the Currently Approved Dose (25 mg/m2) in Postdocetaxel Patients With Metastatic Castration-Resistant Prostate Cancer-PROSELICA. *J Clin Oncol.* 2017;35(28):3198-3206.
6. De Bono JS, Goh JC, et al. KEYNOTE-199: Pembrolizumab (pembro) for docetaxel-refractory metastatic castration-resistant prostate cancer (mCRPC). *Journal of Clinical Oncology* 2018; 36(15): 5007-5007.
7. Fizazi, K., et al., Abiraterone acetate for treatment of metastatic castration-resistant prostate cancer: final overall survival analysis of the COU-AA-301 randomised, double-blind, placebo-controlled phase 3 study. *Lancet Oncol*, 2012. 13(10): p. 983-92.
8. Ryan, C.J., et al., Abiraterone in metastatic prostate cancer without previous chemotherapy. *N Engl J Med*, 2013. 368(2): p. 138-48.
9. Davis ID, Martin AJ, Stockler MR, et al. Enzalutamide with standard first-line therapy in metastatic prostate cancer. *N Engl J Med* 2019;381:121-131.
10. Mateo J, Carreira S, Sandhu S, et al. DNA-repair defects and olaparib in metastatic prostate cancer. *N Engl J Med* 2015;373:1697-1708.
11. Abida W, Patnaik A, Campbell D, et al. Rucaparib in Men With Metastatic Castration-Resistant Prostate Cancer Harboring a

- BRCA1 or BRCA2 Gene Alteration. J Clin Oncol. 2020 Nov 10;38(32):3763-3772.
12. de Bono J, Mateo J, Fizazi K, Saad F, et al. Olaparib for Metastatic Castration-Resistant Prostate Cancer. N Engl J Med. 2020 May 28;382(22):2091-2102.
13. Product Information: ZYTIGA tablet. Abiraterone oral tablets. 2022.
14. Product Information: Erleada Film-Coated Tablets. Apalutamide Film-Coated Tablets. 2022.
15. Product Information: NUBEQA F.C. Tablets. Darolutamide Tablets. 2021.
16. A Study of Niraparib in Combination With Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for Treatment of Participants With Metastatic Prostate Cancer (MAGNITUDE)
17. Clarke NW, Armstrong AJ, Thiery-Vuillemin A, et al. Abiraterone and olaparib for metastatic castration-resistant prostate cancer. NEJM Evidence 2022;1:EVIDoa2200043.
18. Agarwal N, Azad AA, Carles J, et al. Talazoparib plus enzalutamide in men with first-line metastatic castration-resistant prostate cancer (TALAPRO-2): a randomised, placebo-controlled, phase 3 trial. Lancet 2023;402:291-303.

《膀胱癌抗癌藥物治療指引》

Perioperative Chemotherapy of Bladder Cancer

Adjuvant Therapy

Gemcitabine + Cisplatin

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Gemcitabine	1000	1, 8	Q3W	4	1
Cisplatin	70	1	Q3W	4	

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Gemcitabine	1000	1, 8	Q3W	4	1
Cisplatin	35	1, 8	Q3W	4	

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Gemcitabine	1000	1, 8, 15	Q4W	Max 6	2
Cisplatin	70	1	Q4W	Max 6	

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Nivolumab	240 mg	1	Q2W	26*	18

*Up to 1 year

Adjuvant Intravesical Treatment

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
BCG	81 mg	1	QW	6	3

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Mitomycin	30-40 mg	1	QW	6	4-6

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Doxorubicin	40 mg	1	QW	6	7

Intravesical MDP regimen

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Mitomycin	30 mg	1	Q3W	2	7
Doxorubicin	30 mg	8	Q3W	2	
Cisplatin	30 mg	15	Q3W	2	

Neoadjuvant Therapy

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Gemcitabine	1000	1, 8	Q3W	4	1, 2
Cisplatin	70	1	Q3W	4	

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Gemcitabine	1000	1, 8	Q3W	4	1, 2
Cisplatin	35	1, 8	Q3W	4	

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Gemcitabine	1000	1, 8	Q3W	4	1, 2
Cisplatin	35	1, 2	Q3W	4	

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Gemcitabine	1000	1, 8, 15	Q4W	4	1, 2
Cisplatin	70	1	Q4W	4	

Chemotherapy for Metastatic Disease

First-line Therapy

Gemcitabine + Cisplatin

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Gemcitabine	1000	1, 8, 15	Q4W	6	2, 8
Cisplatin	70	2	Q4W		

Gemcitabine + Carboplatin

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Gemcitabine	1000	1, 8	Q3W	4	15
Carboplatin	AUC 4.5	1	Q3W		

DDMVAC

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Methotrexate	30	1	Q2W	6	9, 10
Vinblastine	3	2	Q2W	6	
Doxorubicin	30	2	Q2W	6	
Cisplatin	70	2	Q2W	6	

Gemcitabine + Cisplatin followed by Avelumab

藥品名*	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Gemcitabine	1000	1, 8, 15	Q4W	6	2, 8
Cisplatin	70	2	Q4W		
followed by Avelumab	10 mg/kg	1	Q2W		17

Gemcitabine + Cisplatin followed by Avelumab

藥品名*	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Gemcitabine	1000	1, 8	Q3W	4	15
Carboplatin	AUC 4.5	1	Q3W		
followed by Avelumab	10 mg/kg	1	Q2W		17

DDMVAC followed by Avelumab

藥品名*	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Methotrexate	30	1	Q2W	6	9, 10
Vinblastine	3	2	Q2W	6	
Doxorubicin	30	2	Q2W	6	
Cisplatin	70	2	Q2W	6	
followed by					
Avelumab	10 mg/kg	1	Q2W		17

藥品名*	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Methotrexate	30	1 or 2	Q2W	3-4	9, 10
Vinblastine	3	1 or 2	Q2W	3-4	
Doxorubicin	20-30	1 or 2	Q2W	3-4	
Carboplatin*	AUC 4-5	1	Q2W	3-4	

*For Ccr<60 mL/hr only

PD-1 inhibitor (cisplatin ineligible)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Atezolizumab	1200 mg	1	Q3W		11

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Pembrolizumab	200 mg	1	Q3W		12

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Pembrolizumab	200 mg	1	Q3W		19
Enfortumab vedotin	1.25 mg/kg	1, 8	Q3W		

Radiosensitizing Chemotherapy Regimens for Bladder-Preserving Chemoradiation Following A Maximal TURBT

First-line Therapy

Cisplatin + 5-FU

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Cisplatin	15	1-3	QW	3	14
5-FU	400	1-3	QW	3	

5-FU + Mitomycin C

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Mitomycin C	12	1			13
5-FU	500	1-5, 16-20			

Cisplatin + Paclitaxel

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Cisplatin	15	1-3	QW	3	14
Paclitaxel	50	1	QW	3	

PFL

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Cisplatin	50	1	Q3W	Min 3	16
Leucovorin	50	1-3	Q3W	Min 3	
5-FU	500	1-3	Q3W	Min 3	

Low-dose Gemcitabine for induction therapy

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Gemcitabine	27	1, 4	QW	4	20

Low-dose Gemcitabine for consolidation therapy

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Gemcitabine	27	1, 4	QW	2.5*	20

* Gemcitabine 27 mg/m² delivered twice a week on days 1, 4, 8, 11, and 15 during consolidation therapy

★三院有個別版本

參考文獻

1. Dash A, Pettus JA, Herr HW, et al. A role for neoadjuvant gemcitabine plus cisplatin in muscle-invasive urothelial carcinoma of the bladder: a retrospective experience. Cancer 2008;113:2471-2477.
2. Von der Maase H, Hansen SW, Roberts JT, et al. Gemcitabine and cisplatin versus methotrexate, vinblastine, doxorubicin, and cisplatin in advanced or metastatic bladder cancer: results of a large, randomized, multinational, multicenter, phase III study. J

- Clin Oncol 2000;18:3068-3077.
3. Lamm DL1, Blumenstein BA, Crissman JD, et al. Maintenance bacillus Calmette-Guerin immunotherapy for recurrent TA, T1 and carcinoma in situ transitional cell carcinoma of the bladder: a randomized Southwest Oncology Group Study. J Urol. 2000; 163: 1124-9
4. Lundholm C1, Norlén BJ, Ekman P, et al. A randomized prospective study comparing long-term intravesical instillations of mitomycin C and bacillus Calmette-Guerin in patients with superficial bladder carcinoma. J Urol. 1996; 156: 372-6
5. Solsona E, Iborra I, Ricos JV, et al: Effectiveness of a single immediate mitomycin C instillation in patients with low risk superficial bladder cancer: short and long-term followup. J Urol 1999; 161:1120-1123.
6. Witjes JA1, v d Meijden AP, Collette L, et al. Long-term follow-up of an EORTC randomized prospective trial comparing intravesical bacille Calmette-Guérin-RIVM and mitomycin C in superficial bladder cancer. EORTC GU Group and the Dutch South East Cooperative Urological Group. European Organisation for Research and Treatment of Cancer Genito-Urinary Tract Cancer Collaborative Group. Urology. 1998 ; 52: 403-10
7. Chung-Hsin Chen, Hung-Ju Yang, Chia-Tung Shun, et al. A cocktail regimen of intravesical mitomycin-C, doxorubicin, and cisplatin (MDP) for non-muscle-invasive bladder cancer.
8. Von der Maase H, Sengelov L, Roberts JT, et al. Long-term survival results of a randomized trial comparing gemcitabine plus cisplatin, with methotrexate, vinblastine, doxorubicin, plus cisplatin in patients with bladder cancer. J Clin Oncol 2005;23:4602-4608.
9. Sternberg CN, de Mulder PH, Schornagel JH, et al. Randomized phase III trial of high-dose-intensity methotrexate, vinblastine, doxorubicin, and cisplatin (MVAC) chemotherapy and recombinant human granulocyte colony-stimulating factor versus classic MVAC in advanced urothelial tract tumors: European Organization for Research and Treatment of Cancer Protocol no. 30924. J Clin Oncol 2001;19:2638-2646.
10. Sternberg CN, de Mulder P, Schornagel JH, et al. Seven year update of an EORTC phase III trial of high-dose intensity M-VAC chemotherapy and G-CSF versus classic M-VAC in advanced urothelial tract tumours. Eur J Cancer 2006;42:50-54.
11. Balar AV, Galsky MD, Rosenberg JE, et al. Atezolizumab as first-line treatment in cisplatin-ineligible patients with locally advanced and metastatic urothelial carcinoma: a single-arm, multicentre, phase 2 trial. Lancet 2017;389:67-76.
12. Balar AV, Castellano DE, O'Donnell PH, et al. Pembrolizumab as first-line therapy in cisplatin-ineligible advanced urothelial

- cancer: Results from the total KEYNOTE-052 study population. Clin Oncol 2017;6S:Abstract 284.
13. James ND, Hussain SA, Hall E, et al; BC2001 Investigators. Radiotherapy with or without chemotherapy in muscle-invasive bladder cancer. N Engl J Med 2012;366:1477-1488
 14. Mitin T, Hunt D, Shipley W, et al. Transurethral surgery and twice-daily radiation plus paclitaxel-cisplatin or fluorouracil-cisplatin with selective bladder preservation and adjuvant chemotherapy for patients with muscle invasive bladder cancer (RTOG 0233): a randomized multicentre phase 2 trial. Lancet Oncol 2013;14:863-872.
 15. Pritchard ER, Waddell JA, et al. Gemcitabine and Carboplatin (Renally Dosed) Regimen for Bladder Cancer. Hosp Pharm. 2015; 50(2): 103–107.
 16. Chen WC, Liaw CC. Concurrent cisplatin, 5-fluorouracil, leucovorin, and radiotherapy for invasive bladder cancer. Int. J. Radiation Oncology Biol. Phys 2003; 56(3): 726–733.
 17. Thomas Powles, Se Hoon Park, Eric Voog, et al. Maintenance avelumab + best supportive care (BSC) versus BSC alone after platinum-based first-line (1L) chemotherapy in advanced urothelial carcinoma (UC): JAVELIN Bladder 100 phase III interim analysis. Journal of Clinical Oncology 2020.38.18.
 18. Bajorin DF, Witjes JA, Gschwend JE, et al. Adjuvant nivolumab versus placebo in muscle-invasive urothelial carcinoma. N Engl J Med 2021;384:2102-2114.
 19. Hoimes CJ, Flaig TW, et al. Enfortumab Vedotin Plus Pembrolizumab in Previously Untreated Advanced Urothelial Cancer. J Clin Oncol. 2023 Jan 1;41(1):22-31.
 20. Coen JJ, Zhang P, Saylor PJ, et al. Bladder preservation with twice-a-day radiation plus fluorouracil/cisplatin or once daily radiation plus gemcitabine for muscle-invasive bladder cancer: NRG/RTOG 0712-A randomized phase II trial. J Clin Oncol 2019;37:44-51.

《腎臟癌抗癌藥物治療指引》

Adjuvant Chemotherapy

Clear cell histology

Pembrolizumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Pembrolizumab	200 mg	1	Q3W	Max 17	1

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Sunitinib	50 mg PO QD	1~28	Q6W	Max 1 year	2

參考文獻

1. Choueiri TK, Tomczak P, Park SH, KEYNOTE-564 Investigators, et al . Adjuvant Pembrolizumab after Nephrectomy in Renal-Cell Carcinoma. N Engl J Med. 2021 Aug 19;385(8):683-694.
2. Motzer RJ, Ravaud A, Patard JJ, Pandha HS, et al. Adjuvant Sunitinib for High-risk Renal Cell Carcinoma After Nephrectomy: Subgroup Analyses and Updated Overall Survival Results. Eur Urol. 2018 Jan;73(1):62-68.

Systemic Therapy for Relapse or Stage IV Disease

First-line Therapy for Clear Cell Histology

Risk: Favorable

Preferred Regimens

Axitinib + pembrolizumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Pembrolizumab	200 mg	1	Q3W	Max 35	1
Axitinib	5 mg PO BID				

Cabozantinib + Nivolumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Nivolumab	240 mg	1	Q2W	Max 52	2
Cabozantinib	40 mg PO QD				

Lenvatinib + Pembrolizumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Pembrolizumab	200 mg	1	Q3W	Max 35	3
Lenvatinib	20 mg PO QD	1	Q3W		

Other Recommended Regimens

Axitinib + Avelumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Avelumab	10 mg/kg	1	Q2W		4
Axitinib	5 mg PO BID				

Cabozantinib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Cabozantinib	60 mg PO QD				5

Ipilimumab + Nivolumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Nivolumab	3 mg/kg	1	Q3W	4	6
Ipilimumab	1 mg/kg	1	Q3W	4	
Followed by					
Nivolumab	3 mg/kg	1	Q3W		

Pazopanib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Pazopanib	800 mg PO QD				7

Sunitinib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Sunitinib	50 mg PO QD	1~28	Q6W	9	8

Useful in Certain Circumstances

Active surveillance

High-dose IL-2

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
IL-2	600,000 IU/kg IV Q8H	1~5, 15~19	Q12W	Max 3	10

Axitinib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Axitinib	5 mg PO Q12H				9

Risk: Poor/intermediate Preferred Regimens

Axitinib + pembrolizumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Pembrolizumab	200 mg	1	Q3W	Max 35	1
Axitinib	5 mg PO BID				

Cabozantinib + Nivolumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Nivolumab	240 mg	1	Q2W	Max 52	2
Cabozantinib	40 mg PO QD				

Ipilimumab + Nivolumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Nivolumab	3 mg/kg	1	Q3W	4	6
Ipilimumab	1 mg/kg	1	Q3W	4	
Followed by					
Nivolumab	3 mg/kg	1	Q3W		

Lenvatinib + Pembrolizumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Pembrolizumab	200 mg	1	Q3W	Max 35	3
Lenvatinib	20 mg PO QD	1	Q3W		

Cabozantinib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Cabozantinib	60 mg PO QD				5

Other Recommended Regimens

Axitinib + Avelumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Avelumab	10 mg/kg	1	Q2W		4
Axitinib	5 mg PO BID				

Pazopanib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Pazopanib	800 mg PO QD				7

Sunitinib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Sunitinib	50 mg PO QD	1~28	Q6W	9	8

Useful in Certain Circumstances

Axitinib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Axitinib	5 mg PO Q12H				9

High-dose IL-2

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
IL-2	600,000 IU/kg IV Q8H	1~5, 15~19	Q12W	Max 3	10

Temsirolimus

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Temsirolimus	25 mg	1	QW		11

參考文獻

1. Dash A, Pettus JA, Herr HW, et al. A role for neoadjuvant gemcitabine plus cisplatin in muscle-invasive urothelial carcinoma of the bladder: a retrospective experience. Cancer 2008;113:2471-2477.
2. Von der Maase H, Hansen SW, Roberts JT, et al. Gemcitabine and cisplatin versus methotrexate, vinblastine, doxorubicin, and cisplatin in advanced or metastatic bladder cancer: results of a large, randomized, multinational, multicenter, phase III study. J Clin Oncol 2000;18:3068-3077.
3. Lamm DL, Blumenstein BA, Crissman JD, et al. Maintenance bacillus Calmette-Guerin immunotherapy for recurrent TA, T1 and carcinoma in situ transitional cell carcinoma of the bladder: a randomized Southwest Oncology Group Study. J Urol. 2000;

- 163: 1124-9
4. Lundholm CI, Norlén BJ, Ekman P, et al. A randomized prospective study comparing long-term intravesical instillations of mitomycin C and bacillus Calmette-Guerin in patients with superficial bladder carcinoma. *J Urol*. 1996; 156: 372-6
5. Solsona E, Iborra I, Ricos JV, et al: Effectiveness of a single immediate mitomycin C instillation in patients with low risk superficial bladder cancer: short and long-term followup. *J Urol* 1999; 161:1120-1123.
6. Witjes JA1, v d Meijden AP, Collette L, et al. Long-term follow-up of an EORTC randomized prospective trial comparing intravesical bacille Calmette-Guérin-RIVM and mitomycin C in superficial bladder cancer. EORTC GU Group and the Dutch South East Cooperative Urological Group. European Organisation for Research and Treatment of Cancer Genito-Urinary Tract Cancer Collaborative Group. *Urology*. 1998 ; 52: 403-10
7. Chung-Hsin Chen, Hung-Ju Yang, Chia-Tung Shun, et al. A cocktail regimen of intravesical mitomycin-C, doxorubicin, and cisplatin (MDP) for non-muscle-invasive bladder cancer.
8. Von der Maase H, Sengelov L, Roberts JT, et al. Long-term survival results of a randomized trial comparing gemcitabine plus cisplatin, with methotrexate, vinblastine, doxorubicin, plus cisplatin in patients with bladder cancer. *J Clin Oncol* 2005;23:4602-4608.
9. Sternberg CN, de Mulder PH, Schornagel JH, et al. Randomized phase III trial of high-dose-intensity methotrexate, vinblastine, doxorubicin, and cisplatin (MVAC) chemotherapy and recombinant human granulocyte colony-stimulating factor versus classic MVAC in advanced urothelial tract tumors: European Organization for Research and Treatment of Cancer Protocol no. 30924. *J Clin Oncol* 2001;19:2638-2646.
10. Sternberg CN, de Mulder P, Schornagel JH, et al. Seven year update of an EORTC phase III trial of high-dose intensity M-VAC chemotherapy and G-CSF versus classic M-VAC in advanced urothelial tract tumours. *Eur J Cancer* 2006;42:50-54.
11. Balar AV, Galsky MD, Rosenberg JE, et al. Atezolizumab as first-line treatment in cisplatin-ineligible patients with locally advanced and metastatic urothelial carcinoma: a single-arm, multicentre, phase 2 trial. *Lancet* 2017;389:67-76.
12. Balar AV, Castellano DE, O'Donnell PH, et al. Pembrolizumab as first-line therapy in cisplatin-ineligible advanced urothelial cancer: Results from the total KEYNOTE-052 study population. *Clin Oncol* 2017;6S:Abstract 284.

13. James ND, Hussain SA, Hall E, et al; BC2001 Investigators. Radiotherapy with or without chemotherapy in muscle-invasive bladder cancer. *N Engl J Med* 2012;366:1477-1488
14. Mitin T, Hunt D, Shipley W, et al. Transurethral surgery and twice-daily radiation plus paclitaxel-cisplatin or fluorouracil-cisplatin with selective bladder preservation and adjuvant chemotherapy for patients with muscle invasive bladder cancer (RTOG 0233): a randomized multicentre phase 2 trial. *Lancet Oncol* 2013;14:863-872.
15. Pritchard ER, Waddell JA, et al. Gemcitabine and Carboplatin (Renally Dosed) Regimen for Bladder Cancer. *Hosp Pharm.* 2015; 50(2): 103–107.
16. Chen WC, Liaw CC. Concurrent cisplatin, 5-fluorouracil, leucovorin, and radiotherapy for invasive bladder cancer. *Int. J. Radiation Oncology Biol. Phys* 2003; 56(3): 726–733.
17. Thomas Powles, Se Hoon Park, Eric Voog, et al. Maintenance avelumab + best supportive care (BSC) versus BSC alone after platinum-based first-line (1L) chemotherapy in advanced urothelial carcinoma (UC): JAVELIN Bladder 100 phase III interim analysis. *Journal of Clinical Oncology* 2020.38.18.
18. Bajorin DF, Witjes JA, Gschwend JE, et al. Adjuvant nivolumab versus placebo in muscle-invasive urothelial carcinoma. *N Engl J Med* 2021;384:2102-2114.
19. Hoimes CJ, Flaig TW, et al. Enfortumab Vedotin Plus Pembrolizumab in Previously Untreated Advanced Urothelial Cancer. *J Clin Oncol.* 2023 Jan 1;41(1):22-31.
20. Coen JJ, Zhang P, Saylor PJ, et al. Bladder preservation with twice-a-day radiation plus fluorouracil/cisplatin or once daily radiation plus gemcitabine for muscle-invasive bladder cancer: NRG/TOG 0712-A randomized phase II trial. *J Clin Oncol* 2019;37:44-51.

Systemic Therapy for Non-Clear Cell Histology

Preferred Regimens

Cabozantinib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Cabozantinib	60 mg PO QD				1

Other Recommended Regimens

Lenvatinib + Everolimus

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Lenvatinib	18 mg PO QD				2
Everolimus	5 mg PO QD				

Nivolumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Nivolumab	240 mg or 3 mg/kg	1	Q2W		3, 4

Nivolumab + Cabozantinib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Nivolumab	240 mg or 3 mg/kg	1	Q2W		5
Cabozantinib	40 mg PO QD				

Pembrolizumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Pembrolizumab	200 mg	1	Q2W		6

Sunitinib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Sunitinib	50 mg PO QD	1~28	Q6W	9	7

Useful in Certain Circumstances

Axitinib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Axitinib	5 mg PO Q12H				8

Bevacizumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Bevacizumab	10 mg/kg	1	Q2W		9

Bevacizumab + Erlotinib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Bevacizumab	10 mg/kg	1	Q2W		10
Erlotinib	150 mg PO QD				

Bevacizumab + Everolimus

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Bevacizumab	10 mg/kg	1	Q2W		11
Everolimus	10 mg PO QD				

Erlotinib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Erlotinib	150 mg PO QD				12

Everolimus

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Everolimus	10 mg PO QD				13

Ipilimumab + Nivolumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Nivolumab	3 mg/kg	1	Q3W	4	14
Ipilimumab	1 mg/kg	1	Q3W	4	
Followed by Nivolumab	480 mg	1	Q4W	Max 2 years	

Pazopanib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Pazopanib	800 mg PO QD				7

Temsirolimus

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Temsirolimus	25 mg	1	QW		11

參考文獻

1. Pal SK, Tangen C, Thompson IM, Jr., et al. A comparison of sunitinib with cabozantinib, crizotinib, and savolitinib for treatment of advanced papillary renal cell carcinoma: a randomised, open-label, phase 2 trial. Lancet 2021;397:695-703.
2. Hutson TE, Michaelson MD, Kuzel TM, et al. A single-arm, multicenter, phase 2 study of lenvatinib plus everolimus in patients with advanced non-clear cell renal cell carcinoma. Eur Urol 2021;80:162-170.
3. Koshkin VS, Barata PC, Zhang T, et al. Clinical activity of nivolumab in patients with non-clear cell renal cell carcinoma. J Immunother Cancer 2018;6:9.
4. Product Information: OPDIVO

5. Lee CH, Voss MH, Carlo MI, et al. Phase II trial of cabozantinib plus nivolumab in patients with non-clear-cell renal cell carcinoma and genomic correlates. *J Clin Oncol* 2022;0:JCO2101944.
6. McDermott DF, Lee JL, Ziobro M, et al. Open-label, single-arm, phase ii study of pembrolizumab monotherapy as first-line therapy in patients with advanced non-clear cell renal cell carcinoma. *J Clin Oncol* 2021;39:1029-1039.
7. Product Information: SUTENT
8. Product Information: INLYTA
9. Yang JC, Haworth L, Sherry RM, et al. A randomized trial of bevacizumab, an anti-vascular endothelial growth factor antibody, for metastatic renal cancer. *N Engl J Med* 2003;349:427-434.
10. Srinivasan R, Su D, Stamatakis L, et al. Mechanism based targeted therapy for hereditary leiomyomatosis and renal cell cancer (HLRCC) and sporadic papillary renal cell carcinoma: interim results from a phase 2 study of bevacizumab and erlotinib [abstract]. *Eur J Cancer* 2014;50:8.
11. Voss MH, Molina AM, Chen YB, et al. Phase II trial and correlative genomic analysis of everolimus plus bevacizumab in advanced non-clear cell renal cell carcinoma. *J Clin Oncol* 2016;34:3846-3853.
12. Gordon MS, Hussey M, Nagle RB, et al. Phase II study of erlotinib in patients with locally advanced or metastatic papillary histology renal cell cancer: SWOG S0317. *J Clin Oncol* 2009;27:5788-5793.
13. Armstrong AJ, Halabi S, Eisen T, et al. Everolimus versus sunitinib for patients with metastatic non-clear cell renal cell carcinoma (ASPEN): a multicentre, open-label, randomised phase 2 trial. *Lancet Oncol* 2016;17:378-388.
14. Tykodi SS, Gordan LN, Alter RS, et al. Safety and efficacy of nivolumab plus ipilimumab in patients with advanced non-clear cell renal cell carcinoma: results from the phase 3b/4 CheckMate 920 trial. *J Immunother Cancer* 2022;10.
15. Dutcher JP, de Souza P, McDermott D, et al. Effect of temsirolimus versus interferon-alpha on outcome of patients with advanced renal cell carcinoma of different tumor histologies. *Med Oncol* 2009;26:202-209.